Horizon 2020

Call: H2020-FETOPEN-2016-2017

(FET-Open – Novel ideas for radically new technologies)

Topic: FETOPEN-01-2016-2017

Type of action: RIA

(Research and Innovation action)

Proposal number: 737178

Proposal acronym: SmarTooth

Deadline Id: H2020-FETOPEN-1-2016-2017

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How to fill in the forms

The administrative forms must be filled in for each proposal using the templates available in the submission system. Some data fields in the administrative forms are pre-filled based on the previous steps in the submission wizard.

Proposal ID **737178** *Acronym* **SmarTooth**

1 - General information

Topic	FETOPEN-01-2016-2017
Call Identifier	H2020-FETOPEN-2016-2017
Type of Action	RIA
Deadline Id	H2020-FETOPEN-1-2016-2017

Acronym	SmarTooth
Proposal title	A Bionic Implant to Restore Dental Sensitivity

Note that for technical reasons, the following characters are not accepted in the Proposal Title and will be removed: < > " &

Duration in months	*36*

Please select between 3 and 6 descriptors that best characterise the subject of your proposal, in descending order of relevance. Note that descriptors will be used to support REA services in identifying the best qualified evaluators for your proposal.

Descriptor 1	**Discipline:** Electrical and electronic engineering **Subdiscipline:** Electrical and electronic engineering **Descriptor:** Micro (system) engineering
Descriptor 2	**Discipline:** Materials engineering **Subdiscipline:** Coating and films **Descriptor:** Micro- and nanoelectronics, optoelectronics
Descriptor 3	**Discipline:** Medical engineering **Subdiscipline:** Medical engineering **Descriptor:** Medical engineering, biomedical engineering and technology
Free keywords	*Active medical implantable, Wireless, Neurophysiologic, Evoked somatosensory, Microbattery, Energy harvesting*

Proposal ID **737178** *Acronym* **SmarTooth**

Abstract

SmarTooth is a beyond state of the art bionic device aiming at restoring dental sensitivity resorting to an implant that transforms occlusion mechanical forces into electrical impulses to be delivered to the trigeminal nerve endings. SmarTooth is a new and patented concept which has never been implemented before. It consists of an implantable class 2b medical device, comprising two wirelessly interconnected electronic modules; one in the implanted tooth with force sensing ability and the other interface the trigeminal nerve.

Its design and implementation involve state of the art technologies and critical issues that will require developing new solutions at different levels. Furthermore, the project will develop a comprehensive technology platform for miniaturized medical electronics, comprising all aspects: sensing, data and energy transfer, and biocompatible 3D micro packaging. It should be noticed that these developments are reusable for a number of other medical applications like medical dosing, salivation stimulation and other sensory functions.

SmarTooth transforms dental implants into active prosthesis, restoring dental sensitivity. It is meant for people who need or already have dental implants, to prevent dental overload, mastication motor function impairment, and improving body balance and posture. Six to 10% of the world population have no teeth. In the developed world 130 million teeth are lost each year. In 2014 33 million implants were done worldwide and the market is growing at 6% a year. According to MarketsandMarkets, by 2020 the implant market will represent 46 million units, i. e., an addressable market of €10000 million.

The consortium involves research institutions and staff with long experience in biomedical electronics, sensors and instrumentation, structural mechanics, neurophysiology, oral surgery and dentistry.

Remaining characters 128

Has this proposal (or a very similar one) been submitted in the past 2 years in response to a call for proposals under the 7th Framework Programme, Horizon 2020 or any other EU programme(s)? (•) Yes ( ) No

Please give the proposal reference or contract number.	
713292	

Proposal ID **737178** *Acronym* **SmarTooth**

Declarations

1) The coordinator declares to have the explicit consent of all applicants on their participation and on the content of this proposal.	☒
2) The information contained in this proposal is correct and complete.	☒
3) This proposal complies with ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct).	☒

4) The coordinator confirms:

- to have carried out the self-check of the financial capacity of the organisation on http://ec.europa.eu/research/participants/portal/desktop/en/organisations/lfv.html or to be covered by a financial viability check in an EU project for the last closed financial year. Where the result was "weak" or "insufficient", the coordinator confirms being aware of the measures that may be imposed in accordance with the H2020 Grants Manual (Chapter on Financial capacity check); or	○
- is exempt from the financial capacity check being a public body including international organisations, higher or secondary education establishment or a legal entity, whose viability is guaranteed by a Member State or associated country, as defined in the H2020 Grants Manual (Chapter on Financial capacity check); or	◉
- as sole participant in the proposal is exempt from the financial capacity check.	○

5) The coordinator hereby declares that each applicant has confirmed:

- they are fully eligible in accordance with the criteria set out in the specific call for proposals; and	☒
- they have the financial and operational capacity to carry out the proposed action.	☒

The coordinator is only responsible for the correctness of the information relating to his/her own organisation. Each applicant remains responsible for the correctness of the information related to him/her and declared above. Where the proposal to be retained for EU funding, the coordinator and each beneficiary applicant will be required to present a formal declaration in this respect.

According to Article 131 of the Financial Regulation of 25 October 2012 on the financial rules applicable to the general budget of the Union (Official Journal L 298 of 26.10.2012, p. 1) and Article 145 of its Rules of Application (Official Journal L 362, 31.12.2012, p.1) applicants found guilty of misrepresentation may be subject to administrative and financial penalties under certain conditions.

Personal data protection

Your reply to the grant application will involve the recording and processing of personal data (such as your name, address and CV), which will be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Unless indicated otherwise, your replies to the questions in this form and any personal data requested are required to assess your grant application in accordance with the specifications of the call for proposals and will be processed solely for that purpose. Details concerning the processing of your personal data are available on the privacy statement. Applicants may lodge a complaint about the processing of their personal data with the European Data Protection Supervisor at any time.

Your personal data may be registered in the Early Warning System (EWS) only or both in the EWS and Central Exclusion Database (CED) by the Accounting Officer of the Commission, should you be in one of the situations mentioned in:
-the Commission Decision 2008/969 of 16.12.2008 on the Early Warning System (for more information see the Privacy Statement), or
-the Commission Regulation 2008/1302 of 17.12.2008 on the Central Exclusion Database (for more information see the Privacy Statement) .

Proposal ID **737178** *Acronym* **SmarTooth**

List of participants

#	Participant Legal Name	Country
1	UNIVERSIDADE DO PORTO	Portugal
2	TECHNISCHE UNIVERSITEIT DELFT	Netherlands
3	FONDAZIONE BRUNO KESSLER	Italy
4	FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V.	Germany
5	GADGETWHISPER UNIPESSOAL LDA	Portugal
6	Triteq Ltd	United Kingdom
7	Saliwell Ltd.	Israel

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **UPORTO**

2 - Administrative data of participating organisations

PIC	***Legal name***
999894916	*UNIVERSIDADE DO PORTO*

Short name: UPORTO

Address of the organisation

Street PRACA GOMES TEIXEIRA

Town PORTO

Postcode 4099 002

Country Portugal

Webpage http://www.up.pt

Legal Status of your organisation

Research and Innovation legal statuses

Public body ..... no
Non-profit ..... yes
International organisation ..... no
International organisation of European interest ..... no
Secondary or Higher education establishment ..... yes
Research organisation ..... yes
Legal person ..... yes

Enterprise Data

SME self-declared status ..... 2010 - no
SME self-assessment ..... unknown
SME validation sme ..... unknown

Based on the above details of the Beneficiary Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

NACE Code: 853 - Higher education

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **UPORTO**

Department(s) carrying out the proposed work

Department 1

Department name: Faculdade de Engenharia da Universidade do Porto ☐ not applicable

☐ Same as organisation address

Street: Rua Dr Roberto Frias, s/n

Town: Porto

Postcode: 4200-465

Country: Portugal

Dependencies with other proposal participants

Character of dependence	***Participant***	

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **UPORTO**

Person in charge of the proposal

The name and e-mail of contact persons are read-only in the administrative form, only additional details can be edited here. To give access rights and basic contact details of contact persons, please go back to Step 4 of the submission wizard and save the changes.

Title: Prof. Sex: (•) Male ( ) Female

First name: **Jose** Last name: **MACHADO DA SILVA**

E-Mail: **jms@fe.up.pt**

Position in org.: Associate Professor

Department: Department of Eletrical and Computer Engineering ☐ Same as organisation

☐ Same as organisation address

Street: Rua Dr Roberto Frias, s/n

Town: Porto Post code: 4200-465

Country: Portugal

Website: www.fe.up.pt/~jms

Phone 1: +351225081796 Phone 2: +351966571234 Fax: +351225081443

Other contact persons

First Name	***Last Name***	***E-mail***	***Phone***
Joaquim Gabriel	Mendes	jgabriel@fe.up.pt	+35122 0413411
Pedro	Coeho	pcoelho@fe.up.pt	+351 220413539
Olívia	Rocha	orocha@fe.up.pt	+351 220413542

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **TU Delft**

PIC	***Legal name***
999977366	*TECHNISCHE UNIVERSITEIT DELFT*

Short name: TU Delft

Address of the organisation

Street STEVINWEG 1

Town DELFT

Postcode 2628 CN

Country Netherlands

Webpage www.tudelft.nl

Legal Status of your organisation

Research and Innovation legal statuses

Public body ..... yes

Non-profit ..... yes

International organisation ..... no

International organisation of European interest ..... no

Secondary or Higher education establishment ..... yes

Research organisation ..... yes

Legal person ..... yes

Enterprise Data

SME self-declared status ..... 2015 - no

SME self-assessment ..... 2015 - no

SME validation sme ..... unknown

Based on the above details of the Beneficiary Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

NACE Code: 853 - Higher education

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **TU Delft**

Department(s) carrying out the proposed work

Department 1

Department name: Microelectronics ☐ not applicable

☐ Same as organisation address

Street: Mekelweg 4

Town: Delft

Postcode: 2628 CD

Country: Netherlands

Dependencies with other proposal participants

Character of dependence	***Participant***	

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **TU Delft**

Person in charge of the proposal

The name and e-mail of contact persons are read-only in the administrative form, only additional details can be edited here. To give access rights and basic contact details of contact persons, please go back to Step 4 of the submission wizard and save the changes.

Title: Prof. Sex: (•) Male ( ) Female

First name: **Wouter** Last name: **Serdijn**

E-Mail: **w.a.serdijn@tudelft.nl**

Position in org.: Full Professor of Bioelectronics

Department: Dept. of Microelectronics, Section Bioelectronics ☐ Same as organisation

☐ Same as organisation address

Street: Mekelweg 4

Town: Delft Post code: 2628 CD

Country: Netherlands

Website: http://bioelectronics.tudelft.nl

Phone 1: +31152781715 Phone 2: *+xxx xxxxxxxxx* Fax: +31152785922

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **FBK**

PIC	***Legal name***
999625450	*FONDAZIONE BRUNO KESSLER*

Short name: FBK

Address of the organisation

Street VIA SANTA CROCE 77

Town TRENTO

Postcode 38122

Country Italy

Webpage www.fbk.eu

Legal Status of your organisation

Research and Innovation legal statuses

Public body ..... no

Non-profit ..... yes

International organisation ..... no

International organisation of European interest ..... no

Secondary or Higher education establishment ..... no

Research organisation ..... yes

Legal person ..... yes

Enterprise Data

SME self-declared status ..... 2007 - no

SME self-assessment ..... unknown

SME validation sme ..... 2007 - no

Based on the above details of the Beneficiary Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

NACE Code: 721 - Research and experimental development on natural sciences and engineering

Department(s) carrying out the proposed work

Department 1

Department name: LaBSSAH ☐ not applicable

☐ Same as organisation address

Street: Via Sommarive 18

Town: Povo - Trento

Postcode: 38123

Country: Italy

Department 2

Department name: FBK-CMM / Microsystems research unit ☐ not applicable

☐ Same as organisation address

Street: Via Sommarive 18

Town: Povo - Trento

Postcode: 38123

Country: Italy

Dependencies with other proposal participants

Character of dependence	***Participant***	

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **FBK**

Person in charge of the proposal

The name and e-mail of contact persons are read-only in the administrative form, only additional details can be edited here. To give access rights and basic contact details of contact persons, please go back to Step 4 of the submission wizard and save the changes.

Title: Dr. Sex: ○ Male ◉ Female

First name: **Cecilia** Last name: **Pederzolli**

E-Mail: **pederzo@fbk.eu**

Position in org.: LaBSSAH Managing Director

Department: LaBSSAH ☐ Same as organisation

☐ Same as organisation address

Street: Via Sommarive 18

Town: Povo - Trento Post code: 38123

Country: Italy

Website: http://www.labssah.eu/

Phone 1: +390461314494 Phone 2: +390461314444 Fax: +390461314591

Other contact persons

First Name	*Last Name*	*E-mail*	*Phone*
Anna Maria	Dallaserra	dallaser@fbk.eu	
Sabrina	Delcuratolo	delcuratolo@fbk.eu	

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **Fraunhofer**

PIC	***Legal name***
999984059	*FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V.*

Short name: Fraunhofer

Address of the organisation

Street HANSASTRASSE 27C

Town MUNCHEN

Postcode 80686

Country Germany

Webpage www.fraunhofer.de

Legal Status of your organisation

Research and Innovation legal statuses

Public body ..... no

Non-profit ..... yes

International organisation ..... no

International organisation of European interest ..... no

Secondary or Higher education establishment ..... no

Research organisation ..... yes

Legal person ..... yes

Enterprise Data

SME self-declared status ..... 2007 - no

SME self-assessment ..... unknown

SME validation sme ..... 2007 - no

Based on the above details of the Beneficiary Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

NACE Code: 721 - Research and experimental development on natural sciences and engineering

Proposal ID **737178**	*Acronym* **SmarTooth**	*Short name* **Fraunhofer**

Department(s) carrying out the proposed work

Department 1

Department name: Fraunhofer IZM ☐ not applicable

☐ Same as organisation address

Street: Gustav-Meyer-Allee 25

Town: Berlin

Postcode: 13355

Country: Germany

Dependencies with other proposal participants

Character of dependence	***Participant***	

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **Fraunhofer**

Person in charge of the proposal

The name and e-mail of contact persons are read-only in the administrative form, only additional details can be edited here. To give access rights and basic contact details of contact persons, please go back to Step 4 of the submission wizard and save the changes.

Title: Dr. Sex: (•) Male ( ) Female

First name: **Robert** Last name: **Hahn**

E-Mail: **robert.hahn@izm.fraunhofer.de**

Position in org.: Head of Micro Energy Storage Group

Department: R3S [ ] Same as organisation

[ ] Same as organisation address

Street: Gustav-Meyer-Allee 25

Town: Berlin Post code: 13355

Country: Germany

Website: www.izm.fraunhofer.de

Phone 1: +493046403611 Phone 2: +493031472833 Fax: +493031472835

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **GADGETWHISPER**

PIC	***Legal name***
940278522	*GADGETWHISPER UNIPESSOAL LDA*

Short name: GADGETWHISPER

Address of the organisation

Street Rua Julio Dinis 778 3 Dto

Town Porto

Postcode 4050-322

Country Portugal

Webpage

Legal Status of your organisation

Research and Innovation legal statuses

Public body ..... unknown
Legal person ..... yes
Non-profit ..... unknown
International organisation ..... unknown
International organisation of European interest ..... unknown
Secondary or Higher education establishment ..... unknown
Research organisation ..... unknown

Enterprise Data

SME self-declared status ..... unknown
SME self-assessment ..... unknown
SME validation sme ..... unknown

Based on the above details of the Beneficiary Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

NACE Code: -

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **GADGETWHISPER**

Department(s) carrying out the proposed work

Department 1

Department name: R&D ☐ not applicable

☒ Same as organisation address

Street: Rua Julio Dinis 778 3 Dto

Town: Porto

Postcode: 4050-322

Country: Portugal

Dependencies with other proposal participants

Character of dependence	***Participant***	

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **GADGETWHISPER**

Person in charge of the proposal

The name and e-mail of contact persons are read-only in the administrative form, only additional details can be edited here. To give access rights and basic contact details of contact persons, please go back to Step 4 of the submission wizard and save the changes.

Title: Dr. Sex: (•) Male ( ) Female

First name: **Jorge** Last name: **Marinho**

E-Mail: **jssmarinho@gmail.com**

Position in org.: Chairman

Department: *Please indicate the department of the Contact Point above in the organisation* ☐ Same as organisation

☒ Same as organisation address

Street: Rua Julio Dinis 778 3 Dto

Town: Porto Post code: 4050-322

Country: Portugal

Website:

Phone 1: +351933057105 Phone 2: *+xxx xxxxxxxxx* Fax: *+xxx xxxxxxxxx*

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **Triteq Ltd**

PIC	***Legal name***
998621209	*Triteq Ltd*

Short name: Triteq Ltd

Address of the organisation

Street STATION ROAD STATION YARD UNIT 1

Town HUNGERFORD BERKSHIRE

Postcode RG17 0DY

Country United Kingdom

Webpage www.triteq.com

Legal Status of your organisation

Research and Innovation legal statuses

Public body ..... no

Non-profit ..... no

International organisation ..... no

International organisation of European interest ..... no

Secondary or Higher education establishment ..... no

Research organisation ..... no

Legal person ..... yes

Enterprise Data

SME self-declared status ..... 2014 - yes

SME self-assessment ..... 2014 - yes

SME validation sme ..... 2008 - yes

Based on the above details of the Beneficiary Registry the organisation is an SME (small- and medium-sized enterprise) for the call.

NACE Code: 93 - Sports activities and amusement and recreation activities

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **Triteq Ltd**

Department(s) carrying out the proposed work

No departement involved

Department name ☒ not applicable

☐ Same as organisation address

Street *Please enter street name and number.*

Town

Postcode

Country

Dependencies with other proposal participants

Character of dependence	***Participant***	

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **Triteq Ltd**

Person in charge of the proposal

The name and e-mail of contact persons are read-only in the administrative form, only additional details can be edited here. To give access rights and basic contact details of contact persons, please go back to Step 4 of the submission wizard and save the changes.

Title: Mr. Sex: (•) Male ( ) Female

First name: **Ken** Last name: **Hall**

E-Mail: **ken.hall@triteq.com**

Position in org.: Managing Director

Department: Triteq Ltd ☒ Same as organisation

☒ Same as organisation address

Street: STATION ROAD STATION YARD UNIT 1

Town: HUNGERFORD BERKSHIRE Post code: RG17 0DY

Country: United Kingdom

Website: www.triteq.com

Phone 1: +44 1488684554 Phone 2: *+xxx xxxxxxxxx* Fax: *+xxx xxxxxxxxx*

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **Saliwell**

PIC	***Legal name***
937880682	*Saliwell Ltd.*

Short name: Saliwell

Address of the organisation

Street Hatamar 65

Town Harutzim

Postcode

Country Israel

Webpage www.saliwell.com

Legal Status of your organisation

Research and Innovation legal statuses

Public body ..... no
Non-profit ..... no
International organisation ..... no
International organisation of European interest ..... no
Secondary or Higher education establishment ..... no
Research organisation ..... no
Legal person ..... yes

Enterprise Data

SME self-declared status..... 2012 - yes
SME self-assessment ..... 2012 - yes
SME validation sme..... unknown

Based on the above details of the Beneficiary Registry the organisation is an SME (small- and medium-sized enterprise) for the call.

NACE Code: -

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **Saliwell**

Department(s) carrying out the proposed work

Department 1

Department name: Clinical Dept. ☐ not applicable

☐ Same as organisation address

Street: 65 Hatamar

Town: Harutzim

Postcode: 60917

Country: Israel

Dependencies with other proposal participants

Character of dependence	***Participant***	

Proposal ID **737178** *Acronym* **SmarTooth** *Short name* **Saliwell**

Person in charge of the proposal

The name and e-mail of contact persons are read-only in the administrative form, only additional details can be edited here. To give access rights and basic contact details of contact persons, please go back to Step 4 of the submission wizard and save the changes.

Title: Dr. Sex: (•) Male ( ) Female

First name: **Andy** Last name: **Wolff**

E-Mail: **awolff@zahav.net.il**

Position in org.: President

Department: Clinical Dept. [ ] Same as organisation

[ ] Same as organisation address

Street: 65 Hatamar

Town: Harutzim Post code: 60917

Country: Israel

Website: www.saliwell.com

Phone 1: +972508801852 Phone 2: +972507256338 Fax: +97297461630

Proposal ID **737178** *Acronym* **SmarTooth**

3 - Budget for the proposal

No	Participant	Country	(A) Direct personnel costs/€	(B) Other direct costs/€	(C) Direct costs of sub-contracting/€	(D) Direct costs of providing financial support to third parties/€	(E) Costs of inkind contributions not used on the beneficiary's premises/€	(F) Indirect Costs / € (=0.25(A+B-E))	(G) Special unit costs covering direct & indirect costs / €	(H) Total estimated eligible costs / € (=A+B+C+D+F+G)	(I) Reimburse-ment rate (%)	(J) Max.EU Contribution / € (=H*I)	(K) Requested EU Contribution/ €
1	Uporto	PT	267716	74220	0	0	0	85484,00	0	427420,00	100	427420,00	427420,00
2	Tu Delft	NL	833015	51000	0	0	0	221003,75	0	1105018,75	100	1105018,75	1105018,75
3	Fbk	IT	446973	61900	0	0	0	127218,25	0	636091,25	100	636091,25	636091,25
4	Fraunhofer	DE	584600	64000	6000	0	0	162150,00	0	816750,00	100	816750,00	816750,00
5	Gadgetwhisper	PT	81234	58193	0	0	0	34856,75	0	174283,75	100	174283,75	174283,75
6	Triteq Ltd	UK	314636	45000	0	0	0	89909,00	0	449545,00	100	449545,00	449545,00
7	Saliwell	IL	103200	138203	15000	0	0	60350,75	0	316753,75	100	316753,75	316753,75
	Total		2631374	492516	21000	0	0	780972,50	0	3925862,50		3925862,50	3925862,50

Proposal ID **737178** *Acronym* **SmarTooth**

4 - Ethics issues table

1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve Human Embryonic Stem Cells (hESCs)?	○ Yes ◉ No	
Does your research involve the use of human embryos?	○ Yes ◉ No	
Does your research involve the use of human foetal tissues / cells?	○ Yes ◉ No	
2. HUMANS		**Page**
Does your research involve human participants?	◉ Yes ○ No	5
Are they volunteers for social or human sciences research?	○ Yes ◉ No	
Are they persons unable to give informed consent?	○ Yes ◉ No	
Are they vulnerable individuals or groups?	○ Yes ◉ No	
Are they children/minors?	○ Yes ◉ No	
Are they patients?	○ Yes ◉ No	
Are they healthy volunteers for medical studies?	◉ Yes ○ No	11
Does your research involve physical interventions on the study participants?	◉ Yes ○ No	5
Does it involve invasive techniques?	○ Yes ◉ No	
Does it involve collection of biological samples?	○ Yes ◉ No	
If your research involves processing of genetic information, see also section 4.		
3. HUMAN CELLS / TISSUES		**Page**
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e. section 1)?	○ Yes ◉ No	
4. PERSONAL DATA		**Page**
Does your research involve personal data collection and/or processing?	◉ Yes ○ No	5
Does it involve the collection and/or processing of sensitive personal data (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	○ Yes ◉ No	
Does it involve processing of genetic information?	○ Yes ◉ No	

Does it involve tracking or observation of participants?	◉ Yes ○ No	5
Does your research involve further processing of previously collected personal data (secondary use)?	○ Yes ◉ No	
5. ANIMALS		Page
Does your research involve animals?	○ Yes ◉ No	
6. THIRD COUNTRIES		Page
In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?	◉ Yes ○ No	6
Israel. Partner SaliWell has its headquarters at Israel and delegations in Europe.		
Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?	○ Yes ◉ No	
Do you plan to import any material - including personal data - from non-EU countries into the EU? *For data imports, please fill in also section 4.* *For imports concerning human cells or tissues, fill in also section 3.*	◉ Yes ○ No	6
Data from Israel to EU. More details are provided in page 19 of the technical annex 4-5. The individual identification of the volunteers will be omitted.		
Do you plan to export any material - including personal data - from the EU to non-EU countries? *For data exports, please fill in also section 4.* *For exports concerning human cells or tissues, fill in also section 3.*	○ Yes ◉ No	
If your research involves low and/or lower middle income countries, are benefits-sharing actions planned?	○ Yes ◉ No	
Could the situation in the country put the individuals taking part in the research at risk?	○ Yes ◉ No	
7. ENVIRONMENT & HEALTH and SAFETY		Page
Does your research involve the use of elements that may cause harm to the environment, to animals or plants? *For research involving animal experiments, please fill in also section 5.*	○ Yes ◉ No	

Proposal ID **737178** *Acronym* **SmarTooth**

Does your research deal with endangered fauna and/or flora and/or protected areas?	○ Yes ◉ No	
Does your research involve the use of elements that may cause harm to humans, including research staff? *For research involving human participants, please fill in also section 2.*	○ Yes ◉ No	
8. DUAL USE		Page
Does your research have the potential for military applications?	○ Yes ◉ No	
9. MISUSE		Page
Does your research have the potential for malevolent/criminal/terrorist abuse?	○ Yes ◉ No	
10. OTHER ETHICS ISSUES		Page
Are there any other ethics issues that should be taken into consideration? Please specify	○ Yes ◉ No	

I confirm that I have taken into account all ethics issues described above and that, if any ethics issues apply, I will complete the ethics self-assessment and attach the required documents. ☒

How to Complete your Ethics Self-Assessment

5 - Call specific questions

Open Research Data Pilot in Horizon 2020

If selected, all applicants will participate in the Pilot on Open Research Data in Horizon 2020[1] , which aims to improve and maximise access to and re-use of research data generated by actions. Participating in the Pilot does not necessarily mean opening up all research data. Actions participating in the Pilot will be invited to formulate a Data Management Plan in which they will determine and explain which of the research data they generate will be made open.

Applicants have the possibility to opt out of this Pilot and must indicate a reason for this choice.

Participation in this Pilot does not constitute part of the evaluation process. Proposals will not be evaluated favourably because they are part of the Pilot and will not be penalised for opting out of the Pilot.

We wish to opt out of the Pilot on Open Research Data in Horizon 2020.	○ Yes	◉ No

[1] *According to article 43.2 of Regulation (EU) No 1290/2013 of the European Parliament and of the Council, of 11 December 2013, laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006.*

Data management activities

The use of a Data Management Plan (DMP) is required for projects participating in the Open Research Data Pilot in Horizon 2020, in the form of a deliverable in the first 6 months of the project.

All other projects may deliver a DMP on a voluntary basis, if relevant for their research.

Are data management activities relevant for your proposed project?	◉ Yes	○ No

A Data Management Plan will be delivered (Please note: Projects participating in the Open Research Data Pilot **must** include a Data Management Plan as a deliverable in the first 6 months of the project).	☒
Data Management is part of a Work Package.	☒
Data Management will be integrated in another way.	☐

A Bionic Implant to Restore Dental Sensitivity

Technical annex

Call: H2020-FETOPEN-2016-2017

Topic: FETOPEN-01-2016-2017: FET-Open research and innovation actions

SmarTooth

Abstract: SmarTooth is a beyond state of the art bionic device aiming at restoring dental sensitivity resorting to an implant that transforms occlusion mechanical forces into electrical impulses to be delivered to the trigeminal nerve endings. SmartTooth is a new and patented concept which has never been implemented before. It consists of an implantable class 2b medical device, comprising two wirelessly interconnected electronic modules; one in the implanted tooth with force sensing ability and the other to interface the trigeminal nerve.

Its design and implementation involve state of the art technologies and critical issues that will require developing new solutions at different levels. Furthermore, the project will develop a comprehensive technology platform for miniaturized medical electronics, comprising all aspects: sensing, data and energy transfer, and biocompatible 3D micro packaging. It should be noticed that these developments are reusable for a number of other medical applications like medical dosing, salivation stimulation and other sensory functions.

SmarTooth transforms dental implants into active prosthesis, restoring dental sensitivity. It is meant for people who need or already have dental implants, to prevent dental overload, mastication motor function impairment, and improving body balance and posture. Six to 10% of the world population have no teeth. In the developed world 130 million teeth are lost each year. In 2014 33 million implants were done worldwide and the market is growing at 6% a year. According to MarketsandMarkets, by 2020 the implant market will represent 46 million units, i. e., an addressable market of €10000 million.

The consortium involves research institutions and staff with long experience in biomedical electronics, sensors and instrumentation, structural mechanics, neurophysiology, oral surgery and dentistry, a company with in-house design, manufacturing, research and development capabilities, a company with experience on developing intra-oral devices, and a start-up company that will target future phases of medical certification and commercial exploitation of the SmarTooth as a product.

1. Excellence

1.1 Long-term vision and targeted breakthrough towards that vision

The concept of SmarTooth is based on the patent "Dental abutment with a force transducer interfacing with a nerve" (WO 2010106401 A1, PCT/IB2009/055607[1]) issued by Dr Jorge Marinho, director of GadgetWhisper (GW). This invention comprises a bionic device of transduction of the mastication pressure into an electrical stimulus, capable of being perceived by the organism in the form of a nociceptive stimulus, which triggers an appropriate motor defence response by stopping muscle contraction.

The **SmarTooth project** addresses the **FET Open Research** aiming at building a heterogeneous bionic system – two electronic modules placed in the implanted tooth and close to the trigeminal nerve are interconnected wirelessly – involving the capture and processing of occlusion force signals and stimulation of sensory nerves, which convey those signals to the brain and thus generate a neurologic stimulus and consequent response. It incorporates research and development of a minimally invasive active-implantable medical device (AIMD), comprising a break-through in miniaturization, biocompatible packaging and micro energy supply.

Current dental implants provide bone integration and good performance on chewing and speech, but fail the direct link to the nerve endings which transmit the information that the brain needs to give an adequate muscle response. **Current procedures for teeth replacement are:** 1) removable prostheses used during the day and removed after the meals for cleaning and before bedtime. 2) Fixed prostheses over the implants restrained by fixed and permanent devices, such as abutments and screws adapted to the head or base of the implants. These ensure the stiffness of the set prosthesis/implants, and thus the transmission of the mastication forces to the surrounding bone. The bone sensitivity is vague and imprecise, much like the deep visceral abdominal sensitivity.

The innovations beyond the current state of the art comprise: incorporation of biomedical electronics and sensing technologies into the dental health domain and those brought by the developments in the involved scientific and technical domains:

a) For the accurate **measurement of the applied force** on the tooth, tiny piezoelectric specific sensors will be designed, which can fit in the abutment interface between the tooth crown and the bone implant.

b) Ultra-low power consumption electronic circuits will be designed so that small capacity rechargeable µbatteries that allow the implants to be functional for at least one day (16 to 20 hours) can be used.

c) Signal and power transmission inside the mouth relying on a new radio-frequency (RF) near-field coupling solution will be developed for the communication between sensing (M1) and nerve stimulating (M2) modules.

d) Integrated µbatteries will be used to enable the fitting, in each module, of the application specific integrated circuit (ASIC) and the battery. Novel materials will allow the fabrication of 3D µbatteries revolutionizing the design, functionality and industrial production of such energy devices.

e) Miniaturization: stacked multi-functional system in package integration techniques will be used to implement module M1 as a single piece easily fixable in existing tooth implants. In module M2 the electronic module and battery will fit in a cube of max. 4x4x4 mm^3, around which the coil antenna is wound.

f) New **nerve stimulating µelectrodes** and modules **packaging** solutions will be developed to provide convenient interface with selectivity, good electric characteristics, sensitivity, biocompatibility, and long-term chemical and stimulating stability. A highly effective wafer-level packaging and encapsulation process will be developed which allows parallel manufacturing of hundreds of modules on one substrate.

The final system has to endure exceedingly harsh environmental conditions in terms of electrochemical corrosion, temperature shocks, and mechanical forces. In **technological terms** it is an early stage, high risk visionary technology since never before such an ultra-dense electronic package has been developed which includes energy conversion and storage, sensing and communication functions all together. The complexity of the interdependence of several simultaneous effects, like force sensing and energy generation, occurring in a tiny encapsulation and immersed in the electromagnetic field used for energy and information exchange, which also interact with the semiconducting (ASIC, battery) and conducting materials of the package, is an issue. The biocompatible packaging of such a diversity of materials like piezo ceramic, lithium intercalation electrodes and electrolyte is another big challenge. SmarTooth is being built on the pillars of technological research, product development, and advanced manufacturing that have been considered crucial to promote the conversion of ideas into marketable products identified by the European Commission (EC).

The results and objectives foreseen for the SmarTooth project, in the long-term will provide breakthroughs which will go beyond the development of this specific bionic device and which are not currently foreseen by technology roadmaps. It will then represent a new step in the growth of the overlap between biology and technology. Pressure sensing is commonly used in biomedical engineering and medicine to quantify the mechanical interaction between biomedical interfaces and between tissue and pressure applying devices and surgical instruments. Low-power medical electronics and miniature packaging are essential to develop new portable and/or implantable biomedical devices for both health monitoring and clinical treatment. High efficiency and compact µbatteries are sought for electronic applications in all domains.

1.2 Novelty, non-incrementality, plausibility and foundational character

Increasingly sophisticated functionalities and the reduction of body rejection have promoted the application of medical devices for different purposes[2]. Europe has marked the pace with new breakthroughs achieved in several projects[3]. For instance, the recently concluded STIMULAIS project[4] developed a novel muscular micro-electro-stimulation device for the treatment of adolescent idiopathic scoliosis avoiding bracing and invasive open surgery.

[1] http://www.google.com/patents/US20120064486

[2] Body Implants, Retrieved April 25, 2016 from http://scitechstory.com/impact-areas/body-implants/.

[3] ICT Results. (2008, January 18). Medical Implants: The Inside Story. ScienceDaily. www.sciencedaily.com/releases/2008/01/080116170100.htm.

[4] StimulAIS Report Summary, Project reference 315327, FP7-SME. CORDIS Projects & Results Service, http://cordis.europa.eu/result/rcn/171964_en.html.

Currently, electronic implants that address oral and maxillofacial pathologies are mostly at an incipient stage. In the FP5 project titled "Intelligent micro-sensor, electro-actuated, stimulator of salivary glands" (IST-2001-37409, "Saliwell") an automatic, remote controllable, self-correcting, electronic saliva-stimulating system residing in a dental implant was developed. In 2007 an intra-oral appliance to treat hyposalivation and xerostomia (not sensitivity) named as GenNarino[5] was developed by partner Saliwell. It has received acceptance in Europe, Australia, Israel and is under evaluation by FDA (USA) and was proven to be effective in a number of comprehensive clinical trials.

According to Prof. Mats Trulsson (letter of support in section 5): "We have in our research showed that the normal sensory motor regulation of biting and chewing is severely disturbed when sensory signals from the periodontal receptors around natural teeth are absent.". The impact of teeth lost on the sensory feedback pathway is considerable and leads to sensitivity loss, influencing the control of the jaw function and impairing the fine mandible movement[6]. The jaw is a strategic point of the human body in terms of posture and balance control. Its bad operation may be a cause of postural disorders, headaches, neck pain, dorsal and lumbar disorders. In addition, the patient's inability to control occlusal forces often results in failure of the expensive, time-consuming and painful implant-based rehabilitation, as a result of fractured retaining screws, loose screws, broken solder joints, fractured porcelain and occasionally fractured implants. The link between oral health and overall body health is well documented and backed by robust scientific evidence[7]; 38,7% of cumulative complications in 5 years of use of dental implants are due to overload[8].

The restore of dental sensitivity and muscular control have not yet been addressed. The closest idea we found is the invention DE3444780 that is based on the principle of conducting the sensitivity through the bone surrounding the implant. However, they either interfere with occlusion (splints like the NTI-TSS dental guard) or with the normal muscle neurophysiology discharging electrical pulse (like Grindcare) over the main masticatory muscles, facilitating the occurrence of muscle palsy and tetany with morbid consequence on the recovery of normal balanced occlusion. There are currently no solutions for clinical purposes that can be compared to SmarTooth.

The main novelty of SmarTooth is that when parafunctional movements are detected by the implant's force sensor, data is transferred wirelessly to the neurostimulator implanted on the canine fossa near the sensory trigeminal maxilla or mandible trigeminal sensory ending. This latter device can immediately deliver nociceptive stimuli that run by the sensory pathway to the thalamus and from here directly to the sensorial cortex, leading the brain to produce and generate an adequate motor response that will be conducted to all the masticatory muscles stopping in a more adequate way the parafunctional mastication movements.

The SmarTooth technical approach fosters technologies that lead to a solution with advanced characteristics in performance, efficiency, miniaturisation, and functionality. An ASIC (module M1) will convert the pressure sensor output into a suitable radio-frequency (RF) signal that is relayed by means of near-field coupling onto the trigeminal nerve stimulator (module M2). For the first time piezoelectric sensors have to be developed as small as to fit in the ordinary implant abutments. Experience on using piezoelectric devices and piezo deposition facilities are available at UPorto[9] and at a local private company, Celoplas. Piezo elements are being produced by several industrial partners (e.g. Noliac, or PI). Sandwiches of piezoelectric polymer polyvinylidene fluoride trifluoroethylene (PVDF-TrFE) between two printed metal layers of silver and piezoresistive composites based on multiwall carbon nanotube mixed with polydimethylsiloxane MWCNT/ PDMS have been explored at FBK10.

Wireless RF intra-body communication between two devices has been studied but specific solutions are not known[11,12]. The two modules of each SmarTooth implant have to include tiny rechargeable batteries. This precludes the use of conventional power hungry signal conditioning and data transmission chains. Instead, M1 will perform the charge to RF conversion entirely in the analog/ RF domain, most likely using pulse-density modulation (PDM) or pulse frequency modulation (PFM). Integrate-and-fire techniques, usually found in biomorphic neural circuits will be explored as well. As the communication between the two modules has to be performed in the reactive near field and in a lossy, inhomogeneous, anisotropic medium (viz. the biological tissue), it is foreseen that the radiation and reception efficiency of the antennas, i.e., the efficiency of the conversion from the electric to the electrostatic, magnetostatic or electromagnetic domain and vice versa, is the highest at an impedance level that is very different from the standard 50 Ω. The transmitting antenna and the respective electronic driver need to be co-designed in order to achieve the best conversion efficiency. TUD and UPorto have accumulated experience on developing low-power biomedical and communication electronic electronics.

Regarding nerve stimulation, although preliminary studies[13,14] indicate that square wave pulses 0.2 ms in duration, 4 to 6.5 mA amplitude, 0.7/ second repetition rate can be used, calibration capabilities will be included to allow for adjusting stimulation parameters according to the most efficient trigeminal somatosensory evoked potentials (SEP). The nerve stimulation circuit will employ a recently developed power efficient stimulation strategy that requires a minimum number of external components. This facilitates integration

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[5] S. Fedele, A. Wolff, F. Strietzel, R.M-G. López, S.R. Porter, Y.T. Konttinen, "Neuroelectrostimulation in Treatment of Hyposalivation and Xerostomia in Sjögren's Syndrome: A Salivary Pacemaker", The Journal of Rheumatology Publishing Company Limited, p. 1489, 2008.

[6] Pace-Balzan A, et al., "The responsiveness of the Liverpool Oral Rehabilitation Questionnaire: a pilot study", Int J Prosthodont. 2009 Sep-Oct;22(5):456-8.

[7] Dr Nigel Carter, British Dental Health Foundation, http:/ / www.nhs.uk/ Livewell/ dentalhealth/ Pages/ gum-disease-and-overall-health.aspx

[8] Pjetursson BE, Tan K, Lang NP, Brägger U, Egger M, Zwahlen M. "A systematic review of the survival and complication rates of fixed partial dentures (FPDs) after an observation period of at least 5 years.", I. Implant supported FPDs. Clin. Oral Impl. Res. 15, 2004; 625–642.

[9] J. Cardoso, Nanoscaled piezoelectric energy harvesters, MSc dissertation UPorto, 2015. https:/ / repositorio-aberto.up.pt/ bitstream/ 10216/ 82377/ 2/ 131651.pdf

[10] Saleem Khan et al., Flexible Tactile Sensors Using Screen-Printed P and MWCNT/PDMS Composites, IEEE Sensors Journal, vol. 15, no. 6, June 2015

[11] V. De Santis and M. Feliziani, "Intra-body channel characterization of medical implant devices," 10th International Symposium on Electromagnetic Compatibility, York, 2011, pp. 816-819.

12 Seyedi M, et al, A survey on intrabody communications for body area network applications, IEEE Trans Biomed Eng. 2013 Aug;60(8):2067-79.

[13] Recommendations for the Practice of Clinical Neurophysiology: Guidelines of the International Federation of Clinical Physiology (EEG Suppl. 52). Editors: G. Deuschl and A. Eisenq, International Federation of Clinical Neurophysiology. Elsevier Science B.V. 1999.

[14] Arcuri C, et al,."Somatosensory evoked potentials of inferior alveolar nerve", J Oral Maxillofac Surg. 2006 Apr;64(4):594-9.

into a small module, enhances the reliability of the device and ensures safe charge balancing. FBK will provide support on the design and implementation of custom µelectrodes on a silicon substrate using bulk-micromachining techniques with a diameter of a few microns for ensuring low invasiveness and low tissue damage to stimulate the trigeminal nerves.

Micro-batteries will be developed resorting to technologies being already investigated at Fraunhofer IZM (FHG). A novel battery integration concept based on additive manufacturing technology will be developed. Three 3D processes will be investigated in this part of the project. For the first time it will be possible to directly integrate µbatteries of adapted size into miniaturized electronic medical applications. High aspect ratio battery electrodes will be fabricated much more cost effectively than before and at low temperature, facilitating integration into plastic packages. As state of the art nanomaterials for lithium ion µbatteries will be used, energy density, cycle life, self-discharge and cell voltage will be the same as for conventional batteries. But due to the micro patterning of 3D electrodes much higher currents and shorter charging times will be achieved. So far µbatteries in the ~1 mm length scale have only been reported in the laboratory.

Three options will be investigated to recharge the secondary µbatteries: (1) the main piezo will be optimized to act both as sensor and energy harvesting element. At UPorto harvesting densities of 16 mV/ mm^2 were already achieved[12]; (2) High-frequency energy and inductive power transfer will be evaluated to find the best balance in terms of antenna dimensions, medium propagation, and power conversion efficiency; (3) Infra-red (IR) power transfer with IR power LEDs and photodiodes. Charging time in this case will be shorter which results in higher power requirements for the battery. For the DC/ DC charging circuit, on-chip capacitors eliminate the need for bulky inductors, allowing easier system integration. The approach to be developed here is based on direct current/ voltage load characteristics to be obtained with a true power sensor.

Specific integration techniques available at Triteq will be explored to implement M1 as a single piece easily fixable in the implant abutment and fully compatible with existing tooth implants. Likewise M2 will be implemented as a single piece comprising the electronic module and the rechargeable µbattery, around which the coil antenna is wound. Both modules will be packaged within a biocompatible material.

Key manufacturing challenges to be addressed are: mechanical interconnection of the piezo; 3D stacking and interconnection of chips, inductive coil, battery and other components; electromagnetic distortion of the components; biocompatible housing of piezo and electrolyte battery; long term stable battery encapsulation.

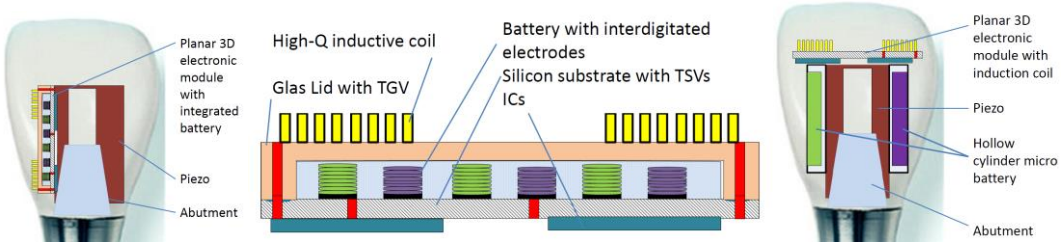


Figure 1 – Vision of SmarTooth integration concepts.

1.3 Research methodology

The SmarTooth research strategy follows a congregation of capabilities and experience in different medical sciences and enabling technologies which are critical to overcome the foreseen challenges and adopts a work plan that promotes a close interaction among experts in the involved scientific and technical domains. Given the critical dependence of the project on the availability of the efficient piezoelectric sensors, communication modules, and power supplies, the first 18 months will be focused on validating the technologies and methods which will ensure the feasibility of the project. In the second half the different blocks of each module will be assembled resorting to specific and biocompatible packaging technologies and pre-clinical trials will be carried out.

The project will start with the development by UPorto, Triteq and FBK of biomechanical studies, i. e., study the force exerted on teeth and the overall biomechanical modelling. These are necessary to formulate the characteristics of the custom force piezoelectric sensors, to evaluate the sensor prototypes, and to provide information on the characteristics of the signals to be acquired. The guidelines of the ISO/ TC106/ SC8-Dental implants Standard will be followed. An already available large scale prototype allows obtaining preliminary validation of the concept and evaluating the characteristics of signal conditioning, data transmission, power consumption, and remote recharge operations. Mechanical studies will allow specifying how the sensor and module M1 will be packaged and attached to the implant abutment - this may have to be adapted to accommodate a ring like sensor and the M1 support. Due to the toxic nature of traditional lead zirconate titanate (PZT) piezoelectrics, lead-free ceramics will be explored, notably bismuth sodium titanate (BNT), bismuth potassium titanate (BKT) (or a compound of both), as well as sodium potassium niobate (KNN) which exhibits relatively high electromechanical and ferroelectric responses. KNN has been explored for 3D piezoelectric scaffolds due to its favourable performance[15]. Other alternatives are the novel perovskite piezoelectrics which have been investigated at UPorto, as well as polymer polyvinylidene fluoride trifluoroethylene between two printed metal layers of silver (Ag) and multiwall carbon nanotube mixed with polydimethylsiloxane investigated at FBK[16]. Devices with different dimensions will be fabricated for validation in the large scale SmarTooth implant and in real dimensions implants.

In parallel, studies to specify the characteristics of modules M1 and M2 will be carried out and the design of these modules within a 180 nm high-voltage MOS technology will be developed by TUD, UPorto, FBK. Included is the design of the antennas – numerical simulations will be performed to ascertain the wireless link at 13.56 MHz between the two modules (previous experience point to using this carrier frequency, but it will be verified whether an alternative Industry, Scientific, Medical or Medical Device Radiocommunications Service band should be used). The transmitting antenna and the electronic antenna driver of M1 will be co-designed to achieve the best antenna

[15] Ahmad Safari, Mehdi Hejazi, "Lead-Free Piezoelectrics", Springer New York, 2012.

[16] Khan Saleem, Dang Wenting, Lorenzelli Leandro, Dahiya Ravinder (2015). Flexible Pressure Sensors based on Screen Printed P(VDF-TrFE) and P(VDF-TrFE)/MWCNTs. IEEE Transactions on Semiconductor Manufacturing, ISSN: 0894-6507, doi: 10.1109/TSM.2015.2468053.

radiation efficiency. The HF energy harvesters will comprise an inductive antenna and a voltage-boosting network followed by a rectifier circuit and a power management unit (PMU) that efficiently charges and loads the battery and supplies the various voltages domains for M1 and M2. Likewise, for the stimulation module M2, the receiving antenna and the electronic antenna readout will be co-designed. In order to prepare the pre-clinical trials the M1 prototype will be developed first (by month 24 of the project). Module M2 will be designed taking into consideration the specificities of the trigeminal stimulating electrode interface.

The fabrication of the 3D µelectrodes at FBK with good electric characteristics, biocompatibility and long-term chemical and stimulating stability, will be based on robust double-sided fabrication technology implementing deep reactive ion etching and anisotropic etching of standard silicon wafers and will allow full 3D control of the probe geometry. The µelectrodes will be metallized by wafer level electrodeposition of gold to improve the transmission of the stimulus. Probes will be assembled by direct bonding to a flexible platform for the interconnections. Different geometries will be evaluated with the aim of i) controlling the initial tissue reactions, ii) achieving high selectivity (i.e. ability to activate one population of neurons without concomitant activation of adjacent neurons), iii) managing implantation associated injury. Microelectrodes performances will be tested in vitro in a first instance by means of advanced single cell electrophysiology in order to evaluate the biocompatibility and the physiological activity of the constituted biohybrid neural interfaces.

To develop the new µbatteries nanomaterials will be used as anode ($Li_4Ti_5O_{12}$, LTO), cathode ($LiFePO_4$ LFP or NCM), and separator (SiO_2, glass, glass-ceramic). Carbon black and nanotubes added to the electrodes will enhance the electrical conductivity and polymer binder (PVDF). This is a completely new approach developed at FHG since so far all electrode pastes were developed only for doctor blading and reel to reel electrode deposition. Innovative formulations for the printing of porous structures will be developed for separator fabrication allowing low-temperature processing. For all those materials the industrial scalability also needs to be achieved: availability of raw materials and scalable fabrication processes. The materials and mixing procedures have to be developed in such a way that after drying or low temperature sintering the required porosity and good particle contact can be established. To enable industrial production, high formulation/ dispersion stability without ink segregation or ageing is required. The components need to stay functional within the inks and these have to have the right viscosity and surface tension for stable and reproducible jetting behaviour.

In the second half of the project, after the fabrication of the two ASICs, the work will focus on the compact integration of modules M1 and M2 jointly carried out by Triteq, UPorto, FBK, TUD and FHG under the supervision of GW and SW given their knowledge on dentistry and stomatology. The preparation of the pre-clinical trials will be started by SW and GW. Here the strategy will be to evaluate first M1 alone with the support of external equipment to evaluate its functionality and thus the effectiveness of module M1 force detection and communication features. The attachment will be disengaged for the dental implant, the M1 module mounted in its place with the sensor located on the buccal aspect, and the attachment returned and positioned above the M1 module. Eventually a new prosthetic appliance will have to be manufactured and fitted to the new arrangement. An external receiver and amplifier will be necessary to receive the emitted signal and apply stimuli to the gum using wires and an occlusal splint to conduct the signals to electrodes placed in contact with the gums in the zones where trigeminal nerve endings can be found. To elucidate whether, when and where the dispatched stimuli are reaching their CNS targets, a number of electrodes placed in the scalp, face and neck muscles connected to an OpenBCI system, will record EEG and EMG signals simultaneously. Brain and muscle activity are recorded simultaneously and averaged (200 averages), to increase the signal-to-noise ratio and to define stimulus-related brain responses. Somatosensory evoked potentials (SSEPs) from the scalp as well as reflex muscles responses are recorded with positioning recording electrode on the scalp at C5 and C6 positions, referred to the Fz site of the 10-20 international electroencephalogram system[17], and should have a typical "W"-shaped response. The source localization is investigated with the sLORETA software. The cortico-muscular coupling based on EEG and EMG recording from masseter muscles during tonic jaw clenching will be evaluated while subjects chew on a peanut. For this purpose, a protocol with specific questions will be prepared. This experiment will be repeated 10 times and one expects to involve at least twenty volunteers.

Concerning the test of M2, to avoid invasive surgery on the voluntary subjects, M2 will be embedded in the occlusal splint. This allows direct wireless communication between M1 and M2 and an evaluation close to the final required operation.

The Consortium is committed to a coherent valorisation strategy based on technology development, certification and commercialization activities. These activities are foreseen in the plan for dissemination and exploitation of the project's results and include: Continuous dissemination of the SmarTooth non-confidential achievements to different stakeholders in the health, scientific, and educational domains; Start-up engagement: GW aims at exploiting the future introduction of the SmarTooth medical device in the market; European collaborative research and development with public research institutions and private industry; High education: academic partners will involve PhD and MSc students in the research tasks to develop their thesis. Students may develop part of that work in collaboration with non-academic partners in order to promote also their entrepreneurship capabilities. This promotes the internationalization of the education process and fosters the integration of the students in an industrial context and in the European dimension.

Gender Issues – The project is strongly committed to creating equal opportunities for women and men as the partners of the SmarTooth consortium are organizations with an established policy of equal opportunities. Notably, gender issues are not considered in the candidates' selection process and the consortium is committed to leverage gender equality and to give the same job opportunities for men and women, based only on merit, competencies and skills. Educating and training the next generation of scientists will play a crucial role in achieving equal representation. The consortium is committed to contribute to a fair gender parity of young researchers choosing a career in science by implementing a policy of working time flexibility in order to better balance the demands of work with other needs of the researchers (e.g., regarding family responsibilities such as child-care, children schools, and healthcare). The consortium will follow the recommendations of the European Technology Assessment Network (ETAN) as well as the "Helsinki Group" on the development and production of statistics and indicators, about the situation of women in scientific research.

[17] Recommendations for the Practice of Clinical Neurophysiology: Guidelines of the International Federation of Clinical Physiology (EEG Suppl. 52). Editors: G. Deuschl and A. Eisenq, International Federation of Clinical Neurophysiology. Elsevier Science B.V. 1999.

1.4 Interdisciplinarity

Developing the SmarTooth device implies a close unconventional collaboration among engineers (electronic and mechanical), biophysicists, neurophysiologists, oral medicine, and system integration specialists. This interdisciplinary approach is essential for the success of the SmarTooth project. It involves knowledge acquired by all partners in domains such as mechanics (UPorto, Triteq), microelectronics (UPorto, TUD, FBK, FHG), micro-technologies and advanced manufacturing (Triteq, FHG, SW), application specific instrumentation (Triteq, SW), neurosciences (SW, GW), all contributing to state of the art and know-how on bringing a new medical bionic device into the market. It wouldn't be possible to implement the project without the involvement of researchers from these different disciplines and the expertise gathered in the respective knowledge domains.

2: Impact

2.1 Impact on technology and/ or society

Impact on Society - SmarTooth will provide the brain efferent information of regulation and modulation of muscle contraction forces of the stomatognathic system, **saving the set implants/ fixed prosthesis from structural stress** overload. This will **decrease the patient's visits to the dental clinic** to repair the installed prostheses. Contributing to a better understanding of texture and hardness of food, he will masticate more effectively with **greater satisfaction and pleasure**. By allowing the perception of the relative position of the mandible in relation to the head and body, provides an improved spatial orientation with gains in motion and balance. It is adaptable to any implant already on the market and thus can be placed in patients who already have dental implants. The abutment based sensor does not imply the adoption of new procedures during surgery. The average price of a procedure for 3 implants (considered the number of replaces when losing the teeth of one quadrant) is around € 8.000. It is estimated that for the patient the final cost of the proposed solution is only 7% more expensive, i. e., €600 per SmarTooth.

Impact on technology – New developments: Miniaturized piezoelectric sensors and energy harvesting processes; New knowledge on electroceuticals, in particular power-efficient neurostimulation and sub- and trans-cutaneous wireless communication; Implantable µelectrodes for specific trigeminal nerve stimulation with expanded portfolio of use cases for clinically driven research; Miniature rechargeable µbatteries with increased power and integration capability; Deeper knowledge of trigeminal nerve physiology and oral neuroscience; Small and zero quiescent power RF techniques which potentiate new applications; Miniaturized heterogeneous and biocompatible packaging.

2.2 Impact on future leadership

Europe in general and the partners of the SmarTooth consortium in particular, will gain and develop new competences and knowledge which will contribute for scientific and industrial leadership, such as: improved knowledge on biomechanics; optimal pressure measurement channel design and implementation; ultra-low power design and electroneurophysiology; power-efficient neurostimulation and sub- and trans-cutaneous wireless communication; enlarge the ability to develop novel intelligent nanomaterials and devices for neuroscience applications and bioelectronics; bringing µbatteries into application; competences to be applied in clinical activity to verify the integrity of alveolar nerve; better prospect of turning scientific research into clinical, societal and commercial relevance; expanded portfolio of use cases for oral neuroscience and clinically driven research.

During the project these developments and competences will promote the training of students, contributing to better qualified professionals. The work plan being proposed allows the development of at least 4 PhD thesis and 8 MSc dissertations. In the future, they will provide a framework to develop other devices using similar technology.

The medical bionic implant global business is expected to reach $17,820 million in 2017[18] and that for dental implants, the market foreseen for the SmarTooth device, is estimated to surpass $ 10,000 million in 2020[19]. Its production and industrialisation involves advanced manufacturing processes in the areas of materials, electronics, and packaging available or to be promoted in Europe. Regarding other medical/ sensor/ electronic applications which can be developed based on the SmarTooth technology platform, a much larger market will be addressed.

2.3 Measures for achieving impact

a) Dissemination and exploitation of results – The identification of the project results will be carried out by the PMC and an exploitation plan will be developed. SmarTooth will generate data from pre-clinical trials (to be carried out by GW at Porto and SW at Israel), handled according to the Declaration of Helsinki, the Oviedo Bioethics convention and the EU Regulation No 536/ 2014 (detailed information in section 5). The project will comply with the Directive 95/ 46/ EC and we ensure that any research activities that will take place after the new regulation has entered into force will comply with the provisions therein.

To ensure an efficient implementation in terms of exploitation of results and IP management the following issues will be handled in the Smartooth project: **Results protection** - The project results will be scrutinized by the Project Management Committee (PMC). Their protection in terms of commercial and industrial exploitation will be then handled by the intellectual property (IP) specialist of each partner organization, who will provide legal support and consulting in patenting, licensing and industrial relations in general. An aggressive Impact and Protection of results (IPR) attitude aiming at valorising the results produced within the consortium will be defined in the Consortium Agreement (CA)[20]; **Organisation and management of the background** - The partners will determine the ownership and access rights among them, including the economic conditions, in the (CA); **Joint ownership** - Results are owned by the partner responsible for

[18] Medical Bionic Implant/ Artificial Organs Market – Trends and Global Forecasts to 2017, Retrieved in 21 April from http:// www.marketsandmarkets.com/ Market-Reports/ medical-bionic-implant-market-908.html.

[19] Dental Implants and Prosthetics Market by Material, Stage, Connectors & Product Type - Global Forecast to 2020. Retrieved in 21 April from http:// www.marketsandmarkets.com/ Market-Reports/ dental-implants-prosthetics-market-695.html

[20] Described in section 3.2. To be signed before the start of the project and based on the © DESCA - Horizon 2020 Model Consortium Agreement (www.DESCA-2020.eu), Version 1.2, 2016.

generating them. In case of jointly owned results, the partners intend to reach an agreement, defined in the CA, for the effective management of the SmarTooth project results. To avoid possible misappropriation and use of information, a non-disclosure agreement will be signed between partners, establishing conditions under which partners disclose information in confidence. Issues on shares, exploitation and licensing to third parties will be taken into consideration. The **Exploitation of results** strategy will be carried out taking into consideration their Technology Readiness Level (TRL). The IPR will be then explored according to the maturity level of the technology envisioned for the project. As a Responsible Research and Innovation (RRI) strategy for SmarTooth it is expected to enable easier access to scientific results from the collaborative research. As so, the PMC will strive for the public SmarTooth results to be made available in the European Open Science Cloud to be created by the European Commission. It has been agreed that the associated costs are predicted in the dissemination costs of the project budget; Concerning **Confidentiality measures,** the terms set out in the CA and in section 5, page 19 of the technical annex 4-5, will be adopted. Confidentiality refers to information that is marked as such and lasts for a period of five years after the end of the project. Jointly developed know-how or business and trade secrets and other IPRs that are not registrable may be used and exploited by all co-owners subject to the contractual confidentiality obligations.

b) Communication activities – The communication strategy (WP6) addresses both public at large and scientific audiences, as well as preliminary contacts to prepare the certification of SmarTooth as a medical device. **Scientific dissemination** (S): - publication of papers in scientific journals and participation in international conferences[21] (on average a total of four per partner); - Organization of seminars and workshops in universities targeting teachers and students; - Development of training material according to Standards in Implant Dentistry. **Promotion** (P): - participation in technology and industrial fairs in the domains of medical equipment and engineering with presentations and demonstrations with proof of concept prototypes for the industry and scientific communities; - Each partner will also use its public relations department to promote the respective achieved results and the SmarTooth system; **Web presence** (W): - web-site displaying different levels of information targeting the general public, the scientific community, and specific technology and medical sectors; - presence in general and professional social networks (e.g., Facebook, LinkedIn); **Marketing** (M): - direct contacts, visits and meetings with associations and companies that influence and recommend/ take the decision on buying SmarTooth. All these activities will raise awareness allowing public engagement, influencing the attitudes of decision-makers and enabling the sector to take future actions. A Fact Sheet (FS) will be available since the beginning outlining the project rationale and objectives, the project's technical baseline, intended target groups and application domains, and detail intermediate and final outputs. This FS will be used in European Commission led dissemination and awareness activities throughout the project lifecycle, and will be published on EC and EC sponsored websites.

3: Implementation

3.1 Workplan and intermediate targets

The work plan of the SmarTooth project is organized in seven work packages (WP) as shown in figure 2.

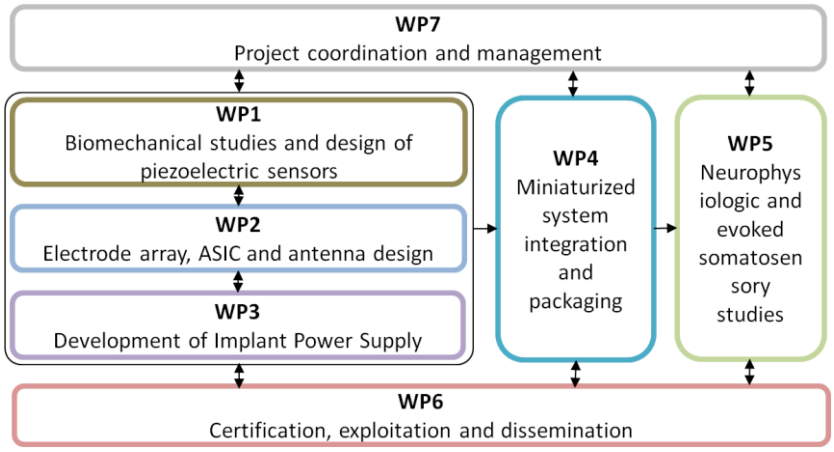


Figure 2 – Overall view of the project work plan.

- **WP1** focuses on the study of biomechanics phenomena using an already existing large scale version of the SmarTooth concept, on the specification and fabrication of the miniature piezoelectric sensors, and on the overall mechanical design of the dental implant.
- **WP2** aggregates the tasks related to the design of the ASICs needed to capture, modulate and transmit the pressure signal in module M1, and to stimulate the trigeminal nerves in module M2, including the nerve stimulating electrodes and the communication antennas.
- **WP3** addresses the development of new rechargeable micro-batteries, as well as the required energy harvesting and battery recharging techniques.
- **WP4** addresses the integration and packaging of the different blocks and supervises the fabrication and assembly of the final fully-integrated miniaturized SmarTooth prototype, as well as its preliminary functional test and verification.
- **WP5** is dedicated to performing the pre-clinical trials with volunteers and evaluate the corresponding neurophysiologic and somatosensory feedback provided by the SmarTooth prototype. Two additional work packages run along the whole duration of the project.

[21] IEEE Transactions on Biomedical Engineering, IET Healthcare Technology Letters, International Journal of Oral Science, Clinical Implant Dentistry and Related Research, IEEE Sensors Journal, IEEE Journal of Solid-State Circuits; and in conferences and workshops such as IEEE/ ACM Design, Automation and Test in Europe (DATE), IEEE International Symposium on Circuits and Systems (ISCAS), International Congress of Oral Implantologists (ICOI)

- **WP6** congregates the different communication and dissemination initiatives and starts preparing the future certification and exploitation of the SmarTooth medical device.
- **WP7** is dedicated to the overall coordination and management of the project. An effort was made to avoid unnecessary dependencies when organizing the WPs, thereby minimizing the probability of delays and development conflicts among tasks.

Seven milestones (MS) are established concerning intermediate targets and critical results:

- **MS1** (M1) Website online and Fact Sheet issued.
- **MS2** (M10) first specification and validation of piezoelectric sensors, block diagrams of modules M1 and M2 defined, and energy specification completed.
- **MS3** (M18) Conclude the validation of the piezoelectric sensors; the ASIC of M1 is sent for fabrication; the antennas are designed and characterized; the fabrication process of the 3D electrode arrays is defined and validated; the micro-battery recharging technique is defined and validated; the concept and specifications to integrate and package all the elements in modules M1 and M2 are defined; clinical and ethical protocols are submitted for approval in order to be ready by month 30. Dissemination and training material according to the dissemination plan is available.
- **MS4** (M24) The external battery charger and controller to define M2 parameters is validated; the ASIC for module M2 is sent for fabrication; final prototypes of the nerve stimulating electrode arrays are validated; 3D electrodes and functional structures for electrochemical evaluation of the micro-batteries are ready; the overall mechanical properties of SmarTooth are defined.
- **MS5** (M28) the prototypes of the micro-battery with built-in charging circuit are validated; the technology to ensure the biocompatible integration and electrical interconnection of micro-batteries and chips is defined; by this time training workshops for health students and professionals will have taken place and results of evaluation are available; training material focusing on engineering and technological issues is prepared.
- **MS6** (M30) Functional and electric tests of the M1 and M2 ASICs are concluded; modules M1 and M2 are fully integrated and first experiments with SmarTooth are carried out; the approval of the clinical ethical is received.
- **MS7** (M36) The results of the pre-clinical trials after analysis of somatosensory data are available and a fully evaluation of SmarTooth performance will have been carried out; new dissemination material is available; the strategic plan for the future exploitation of SmarTooth, including the full definition of the certification process is defined.

Three progress reports (M10, M18, M28) and a final report will be issued. The overall timing of the tasks is shown in figure 3.

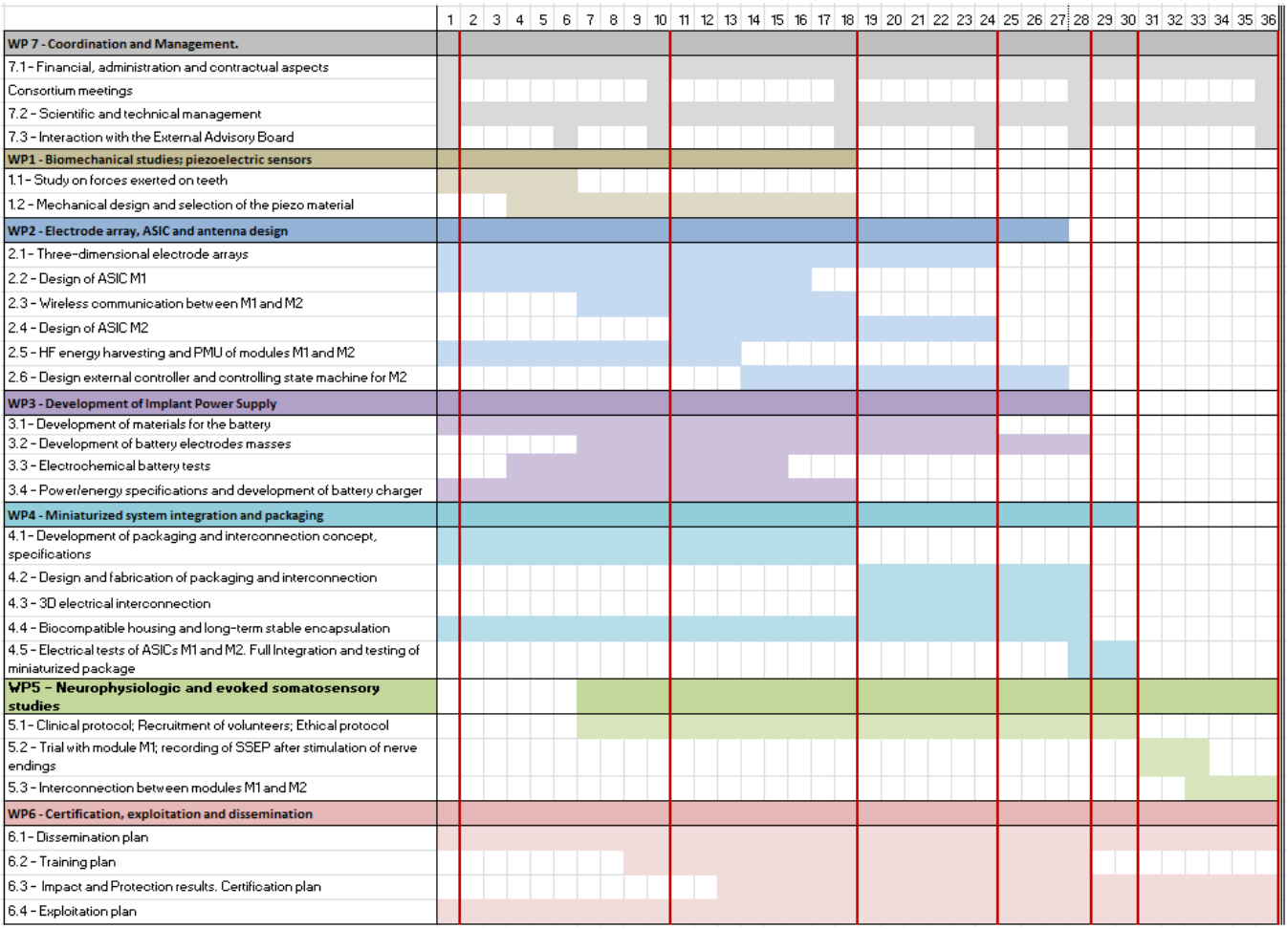


Figure 3 – SmarTooth work plan scheduling – red lines identify the verification of the milestones.

Table 3.1 – Project reporting periods.

Proposed length of the project (months)	RP1 duration(months)	RP2 duration (months)	RP3 duration (months)	RP4 duration (months)
36	10	8	10	8

Table 3.1.a – Work packages description.

Work package number	**1**	**Start M1 – End M18**				**Leader: UPorto**	
Work package title	**Biomechanical studies and design of piezoelectric sensors**						
Participant number	1	2	3	4	5	6	7
Short name of participant	UPorto	TUD	FBK	FHG	GW	Triteq	SW
Person/ months per participant:	25		13		7		
Objectives – Biomechanical study of forces exerted on teeth; Design, implementation, and validation of the fabricated piezoelectric sensors; Development of a 3D mechanical model of forces and mechanical stress in the prototype implant; Evaluation of the piezoelectric sensors for energy harvesting.							
Description of work **Task 1.1 Study of the forces exerted on teeth [UPorto, GW]** – Use mechanical press and Tekscan© (device that measures biting forces) to formulate the specifications for sensors to be fabricated, including occlusal force, timing and location; develop a 3D finite element model and simulate SmarTooth to evaluate mechanical properties. **Task 1.2 Mechanical design and selection of the piezo material [UPorto, FBK, GW]** – Validate the fabricated piezoelectric sensors. Test devices to assess the amount of energy that can be harvested and determine which mechanical characteristics should be enhanced in order to ensure a behaviour compatible with both pressure sensing and energy harvesting.							
Deliverables **D1.1 (M06) – Report**: Dental biomechanics study and piezoelectric sensors: forces exerted on teeth; 3D finite element model; first evaluation of the piezoelectric sensors. **D1.2 (M18) – Report and prototype:** Specifications and validation of the fabricated piezoelectric sensors.							

Work package number	**2**	**Start M1 – End M27**				**Leader: TUD**	
Work package title	**Electrode array, ASIC and antenna design**						
Participant number	1	2	3	4	5	6	7
Short name of participant	UPorto	TUD	FBK	FHG	GW	Triteq	SW
Person/ months per participant:	45	96	68				
Objectives Design of two different integrated circuits, M1 and M2 to integrate sensory readout, neurostimulation, wireless communication and high-frequency (HF) energy harvesting units. Design of the electrode arrays for integration into module M2 and of the antennas for modules M1 and M2.							
Description of work **Task 2.1 Three-dimensional electrode arrays [FBK]** – fabrication of the 3D electrode arrays to interface module M2 with the trigeminal nerve endings on a silicon substrate by bulk-micromachining techniques with a diameter of a few microns for ensuring low invasiveness and low tissue damage. In-vitro tests will be conducted by means of advanced single cell electrophysiology in order to evaluate the biocompatibility and the physiological activity of the biohybrid neural interfaces. **Task 2.2 ASIC M1 [TUD]** – develop the part of ASIC M1 that receives the sensory data from the piezo-sensor and converts its electric charge into a suitable RF signal that is relayed onto M2. To save energy, M1 will perform the charge-to-RF conversion entirely in the analog/ RF domain. **Task 2.3 Wireless communication [TUD]** – develop the interface based on EM-field simulations and in-vitro experiments; computed the link budget and design the antennas for M1 and M2, taking into account physical limitations and surroundings imposed by implants. **Task 2.4 ASIC M2 [TUD]** – develop the receiver and neurostimulator ASIC M2 after specifications provided by SW and FBK. **Task 2.5 HF energy harvesting [TUD]** – develop the HF energy harvesting (HFEH) and PMU of modules M1 and M2. **Task 2.6 External controller and controlling state machine of M2 [UPorto]** – develop the state machine to control the operation of M2 and the external device to control and regulate the stimuli characteristics of module M2 and to charge the µbatteries.							
Deliverables **D2.1 (M03) [TUD, UPorto] - Report**: M1 and M2 block diagrams and specifications. **D2.2 (M16) [TUD, UPorto] – Report and gds files**: Circuit definition of the M1 ASIC blocks (excl. power supply): sensor signal conditioning, modulator, transmitter, antenna interface. Antenna design and electrical characterization. **D2.3 (M12) [FBK] - Report and prototypes**: Definition of the fabrication process for the 3D electrode arrays, preliminary test structures and in vitro functional trials. **D2.4 (M24) [TUD, UPorto] – Report and gds files:** Schematics of the M2 ASIC blocks: receiver, control and neural stimulator. **D2.5 (M24) [FBK]– Report and prototypes:** Fabrication process of the microprobes and final prototypes. **D2.6 (M27) – Report and prototype**: Specifications and validation of the external controller.							

Work package number	**3**	**Start M1 – End M28**				**Leader: FHG**	
Work package title	**Development of Implant Power Supply**						
Participant number	1	2	3	4	5	6	7
Short name of participant	UPorto	TUD	FBK	FHG	GW	Triteq	SW
Person/ months per participant:	32	2		46		12	
Objectives – Characteristics and development of specific **µbatteries for integration in modules M1 and M2** and the respective							

recharging process and technology by energy harvesting or power transfer.

Description of work

Task 3.1: Development of materials for the battery [FHG] - Nanomaterials will be used as anode, cathode, and separator. Additional additives and solvents will be added and particle dimensions adapted such that the rheology is optimized for 3D stacked printing, electrophoretic deposition (EPD) and jetting.

Task 3.2: Development of battery electrodes masses [FHG] - Two processes will be developed: the jet-process will be used primarily for the separator and the 3D printing for the electrodes. Jetting of electrodes will be developed as a back-up solution. For ultra-high power requirements the IZM EPD process can also be adapted. The second process is 3D stacked precision print of interdigitated battery electrodes. The main objective is the development of sufficiently good scaled industrial fabrication processes, i.e., realising stack printing from 8 to 50 layers on a material deposition of 5 to 25µm per layer. Formulation components, additives electrode and separator materials will be screened to create and optimize a fully functional 3D µbattery.

Task 3.3 Electrochemical battery tests [FHG] – Using IZMs micro encapsulation and microfluidic electrolyte dosing technology, complete test cells will be fabricated and electrically tested (CV curves, cycling).

Task 3.4: Power/ energy specifications and development of battery charger [FHG, UPorto, Triteq, TUD] – Specifications for the batteries charger. Design of the battery charge controlling circuit according to the characteristics provided by FHG. An electronic circuit will be implemented within a power budget suitable for <µW-level harvesting (high-frequency, inductive link, infra-red and piezo energy harvesting). Maximum human radiation exposure and tissue heating will be considered. The wireless link will be developed in close cooperation to task 2.5. For the DC/ DC converter switched-capacitor topologies will be developed for higher efficiency at high conversion ratio and low load current.

Deliverables

D3.1 (M6) [FHG, UPorto, Triteq, TUD] – Report. Power supplies specifications for modules M1 and M2.

D3.2 (M18) [Triteq] Report – Best suited battery recharging technical option.

D3.3 (M24) [FHG] – Report, prototype: First jet-dispensed 3D electrodes and functional structures for electrochemical evaluation.

D3.4 (M28) [FHG, UPorto, Triteq, TUD] Report and prototype – Micro-battery with built-in charging circuit.

Work package number	**4**	**Start M1 – End M30**			**Leader: Triteq**	
Work package title	**Miniaturized system integration and packaging**					
Participant number	1	2	3	4	5	6	7
Short name of participant	UPorto	TUD	FBK	FHG	GW	Triteq	SW
Person/ months per participant:	30	4	22	24	1	82	1

Objectives – Integration and biocompatible miniaturized packaging of the different blocks and fabrication/ assembly of the final fully-integrated miniaturized SmarTooth prototype. The final system has to endure exceedingly harsh environmental conditions in terms of electrochemical corrosion, temperature shocks, and mechanical forces.

Description of work

Task 4.1: Development of packaging and interconnection concept, specifications [GW, Triteq, FBK, FHG] – Several integration concepts, component placements and biocompatible encapsulation will be modelled and evaluated: planar stacking of chips and components, planar battery integration, cylindrical battery integration, piezo integration and its mechanical connection. An analysis on the tooth prosthesis mechanical design of the pressure sensors, antenna, modules M1 and M2, nerve stimulating electrode, and battery (including charger) packaging models will be carried out. Finite element analysis of the SmarTooth device and operation, identifying any points of mechanical weakness or areas of concern will be carried.

Task 4.2: Design and fabrication of packaging and interconnection [UPorto, FHG, Triteq, GW, SW] - Review and critique the design of the abutment and analyse the fit of sub-components taking into account manufacturing tolerance stacks, assembly and insertion. The 3D CAD model developed in task 1.1 will form a foundation for further mechanical work to module the pressure sensor, antenna and M1 and M2 packaging modules of a representative size.

Task 4.3: 3D electrical interconnection [UPorto, FHG, TUD, Triteq] – Depending on the integration concept, several options for interconnection have to be developed, like wire bonding, flexible connector and solder of stacked chips with through-vias. Due to the 3D-stacking and integration concept, vertical interconnects between silicon/ glass chips using TSV and TGV and interconnected by means of solder or anisotropical conductive adhesive will be used. Ultra-thin wire or flexible printed circuit board interconnects will be investigated. Direct write vertical conductive tracks on the piezo element are another option.

Task 4.4 Biocompatible housing and long-term stable encapsulation [FBK, FHG, Triteq] – Study of biocompatibility and biostability issues to improve tolerance of the implant by the host, and to prevent reduction of sensor performance due to contact with biological fluids. Develop new encapsulation package to overcome ceramic and titanium housings for total versatile implants. A PDMS-based package will be implemented, but to improve the long-term stability of the implants multilayer polymeric package, will be also evaluated. In vitro trials to test the resistance of the package to a simulated biological environment and to assess the response of selected neuronal cell lines.

Task 4.5 Full integration and testing of miniaturized package [UPorto, TUD, FBK, FHG, Triteq, GW, SW] – Test of the fabricated M1 and M2 modules. Final integration and packaging of the different blocks; fabrication, assembly and functional test of the fully-integrated SmarTooth prototype. A test system will be defined and manufactured to allow representative and repeatable tests to be carried out. The prototype samples will be investigated to assess the physical and electronic performance and will become the focus of the final evaluation tests.

Deliverables

D4.1 (M18) [Triteq]: Report – Modules integration, packaging concept and specifications.
D4.2 (M24) [Triteq]: Report – SmarTooth mechanical properties - constrains and packaging technologies.
D4.3 (M28) [FBK, FHG]: Report - Battery and chip biocompatible integration and electrical interconnection technology.
D4.4 (M30) [All] - Report and prototype: Functional and electric tests of the M1 and M2 ASICs. Full system integration and final evaluation testing.

Work package number	**5**	**Start M7 – End M36**				**Leader: SW**	
Work package title	**Neurophysiologic and evoked somatosensory studies**						
Participant number	1	2	3	4	5	6	7
Short name of participant	UPorto	TUD	FBK	FHG	GW	Triteq	SW
Person/ months per participant:	3	1	1	1	8	1	11

Objectives – Assess the mechanical and physiological performance of the M1 module in the oral cavity, and its usability by dentists and patients. Assess the communication between modules M1 and M2 and the nerve stimulating capability of module M2. Verify the connection of SmarTooth with the cortex and brainstem relays regulating chewing and teeth sensory mechanisms as well as the activation of the masticatory muscles.

Description of work

Design: Randomized, sham controlled, cross-over, double-blind trial. A sham (inactive) M1 module will serve as a control.
Subjects: 20 volunteers will be enrolled. They must healthy and have (1) at least one dental implant in the anterior segment of the lower jaw, (2) an implant-retained patient self-removable lower prosthesis, (3) at least one attachment, i.e., a device mounted on one of the implants that retrievably attaches the prosthesis to the implant.
Task 5.1 - Clinical protocol; Recruitment of volunteers; Ethical protocol [SW, GW]: Preparation of external equipment. Elaboration of the medical protocol to conduct the pre-clinical trials. Recruitment and evaluation of the volunteers. Preparation and submission of the ethical protocol to the ethical committee. These procedures will be carried out under the supervision of the External Advisory Board (EAB).
Task 5.2 – Test with module M1; recording of SSEP after stimulation of nerve endings [SW, GW]: module M1 will be inserted on the buccal side of an existing implant and connected to external equipment (such as Matrix line by Micromed) to trigger a programmable pattern of electric stimuli to the trigeminal endings in the gum using a specific occlusal gutter to support the electrodes.
Task 5.3 – Interconnection between modules M1 and M2 [SW, GW]: To fully evaluate the SmarTooth device, trials will be performed using both M1 and M2 modules. To avoid the surgery needed to implant the receiver/ stimulator (M2), the operation will be tested using M1 as in task 5.2, but M2 is placed in an occlusal gutter to apply stimuli on the gum of the volunteer. M2 captures the signal emitted from M1 and applies the stimuli. Again SSEPs will be captured and analysed.

Deliverables

D5.1 (M18) [SW, GW]: **Report** – Clinical and Ethical protocols; Approval by the Ethical committee
D5.2 (M36) [SW, GW]: **Prototype** – Pre-clinical trials: 20 dental appliances adapted to the attachment mounted on top of the M1 module on one of the dental implants and specific occlusal gutter integrating a M2 module.
D5.3 (M36) [SW, GW]: **Report** – Evaluation of SmarTooth performance. Analysis of somatosensory data.

Work package number	**6**	**Start M1 – End M36**				**Leader: GW**	
Work package title	**Certification, exploitation and dissemination**						
Participant number	1	2	3	4	5	6	7
Short name of participant	UPorto	TUD	FBK	FHG	GW	Triteq	SW
Person/ months per participant:	6	4	2	1	8	2	1

Objectives – To create awareness of the SmarTooth in scientific and industrial communities.

Description of work

Task 6.1 – Dissemination plan [All] – Project Fact Sheet. Creation and updating of the web-site; posts in Facebook and LinkedIn; presentations to the scientific community (conference and journal papers); pre-competitive information to the industry
Task 6.2 – Training plan [All] – Design and implement open trainings using novel and enthusiastic methods for academic researchers and students.
Task 6.3 – Certification plan IPR Plan [GW, UPorto] – To bridge the "valley of death" by moving a first step toward the full commercial exploitation of the SmarTooth, ensuring that a sound framework allows for potential future clinical trial or regulatory approval is in place. Research and develop a fair and effective way to protect IPR globally while encouraging the adoption and use of the SmarTooth certification.
Task 6.4 – Exploitation plan [All] – Provide information about the potential results of the project and define a proactive behaviour to protect them. Market analysis to identify dimension, key players and needs to allow the consortium to react to changes and adapt the investigations to the business model. Prepare future exploitation after the project.

Deliverables

D6.1 (M1) [GW]: Dissemination and exploitation plans. Fact Sheet. Creation and maintenance of the website and its dissemination.
D6.2 (M6) Data Management plan [GW]: Description of the data management life cycle for all data sets that will be collected, processed or generated by the research project.
D6.3 (M18) [All]: First set of scientific publications; brochure for distribution in public events; training material targeting health

students and professionals. IPR plan.
D6.4 (M28) [All]: **Report**. Assessment of training workshop. Results of questionnaire to participants in the training workshop. **Training material** targeting engineering students and professionals.
D6.5 (M36) [All]: **Final dissemination report**. Assessment of dissemination activities. Future exploitation plan. Certification process.

Work package number	**7**	**Start M1 – End M36**				**Leader: UPorto**	
Work package title	**Project coordination and management**						
Participant number	1	2	3	4	5	6	7
Short name of participant	UPorto	TUD	FBK	FHG	GW	Triteq	SW
Person/ months per participant:	25	2	2	2	2	2	2

Objectives - Ensure the executive and scientific coordination of the project, the execution of all legal, technical and financial aspects. Serve as an intermediate between project partners and the European Commission.

Description of work
Task 7.1 Financial, admin and contractual aspects [UPorto] – management of all administrative, financial, contractual and legal aspects of the project, as well as other general societal, data management, ethical or security issues.
Task 7.2 Scientific and technical management [Steering Committee] – scientific and technical supervision of the project; Monitor the project progress against foreseen milestones, goals and deliverables and act in case corrective measures are needed; Hold regular meetings with the EAB.
Task 7.3 Interaction with the External Advisory Board [Project Management Committee] – obtain external feedback on SmarTooth work/ results from independent academic and industry experts who will provide recommendations about best practices and methods for the best exploitation of the project results.

Deliverables
D7.1 (M1) – **Report**: Project and data management plan (including a work risk log);
D7.2 (M10) – **Report**: Progress Report 1 with assessment of the milestones foreseen for month 10. Includes collaboration for the statistics and indicators, about the situation of women in scientific research.
D7.3 (M18) – **Report**: Progress Report 2 with assessment of the milestones foreseen for month 18.
D7.4 (M28) – **Report**: Progress Report 3 with assessment of the milestones foreseen for month 28.
D7.5 (M36) – **Report**: Final Report of the SmarTooth Project.

Table 3.1b: List of work packages

WP No	Work Package Title	Lead Participant	Lead Participant	Person-Months	Start Month	End month
1	Biomechanical studies; piezoelectric sensors	1	UPorto	45	1	18
2	Electrode array, ASIC and antenna design	2	TUD	209	1	27
3	Development of Implant Power Supply	4	FHG	92	1	28
4	Miniaturized system integration and packaging	6	Triteq	164	1	30
5	Neurophysiologic and evoked somatosensory studies	7	SW	26	7	36
6	Certification, exploitation and dissemination	5	GW	24	1	36
7	Project coordination and management	1	UPorto	36	1	36
				584		

Table 3.1c: List of Deliverables

Deliverable	Deliverable name	WP #	Lead partner	Type	Dissemination level	Delivery date
D1.1	Dental biomechanics study and piezoelectric sensors	1	UPorto	R, Other	PU	M06
D1.2	Specifications and validation of the fabricated piezoelectric sensors.	1	UPorto	R, DEM	PU	M18
D2.1	Modules M1 and M2 block diagrams and specifications	2	TUD	R	CO	M03
D2.2	Circuit definition of the M1 ASIC blocks (excl. power supply). Antenna design and electrical characterization.	2	TUD	R, other	CO	M16
D2.3	Definition of the fabrication process for the 3D electrode arrays,	2	FBK	R, DEM	PU	M12
D2.4	Schematics of the M2 ASIC blocks (excl. power supply).	2	TUD	R, other	CO	M24
D2.5	Fabrication process of the electrode arrays and final prototypes.	2	FBK	R, DEM	PU	M24
D2.6	Specifications and validation of the external controller.	2	UPorto	R, DEM	CO	M27
D3.1	Power supplies specifications for modules M1 and M2.	3	UPorto	R	PU	M06
D3.2	Best suited battery recharging technical option.	3	Triteq	R,DEM	PU	M18
D3.3	First jet-dispensed 3D electrodes and functional structures for electrochemical evaluation.	3	FHG	R	PU	M24
D3.4	Micro-battery built with built-in charging circuit	3	FHG	R,DEM	PU	M28
D4.1	Modules integration, packaging concept and specifications	4	Triteq	R	CO	M18

D4.2	SmarTooth mechanical properties –constrains and packaging technologies	4	Triteq	R	CO	M24
D4.3	Battery and chip biocompatible integration and electrical interconnection technology	4	FBK	R	CO	M28
D4.4	Functional and electric tests of the M1 and M2 ASICs. Full system integration and SmarTooth evaluation testing.	4	UPorto	R, DEM	CO	M30
D5.1	Submission to approval of the Clinical and Ethical protocols to Ethical committee;	5	GW	R	PU	M18
D5.2	Pre-clinical trials	5	SW	Other	CI	M36
D5.3	Evaluation of SmarTooth performance. Analysis of somatosensory data.	5	SW	R	CO	M36
D6.1	Dissemination and exploitation plans; Fact Sheet; Creation of the website, logo and dissemination of its link.	6	GW	DEC	PU	M01
D6.2	Data Management plan	6	GW	R	PU	M06
D6.3	Scientific publications; Brochure; Training material; IPR plan	6	GW	R, other	PU	M18
D6.4	Assessment of training workshop; Training material	6	GW	R,other	PU	M28
D6.5	Scientific publications; Exploitation plan; Strategy for future certification process.	6	GW	R, other	PU	M36
D7.1	Project and data management plan (including a work risk log)	7	UPorto	R, other	PU	M1
D7.2	Progress Report 1 with assessment of the milestones.	7	UPorto	R	CO	M10
D7.3	Progress Report 2 with assessment of the milestones.	7	UPorto	R	CO	M18
D7.4	Progress Report 3 with assessment of the milestones.	7	UPorto	R	CO	M28
D7.5	Final report	7	UPorto	R	CO	M36

A detailed project organisation is shown in figure 2 (Pert chart).

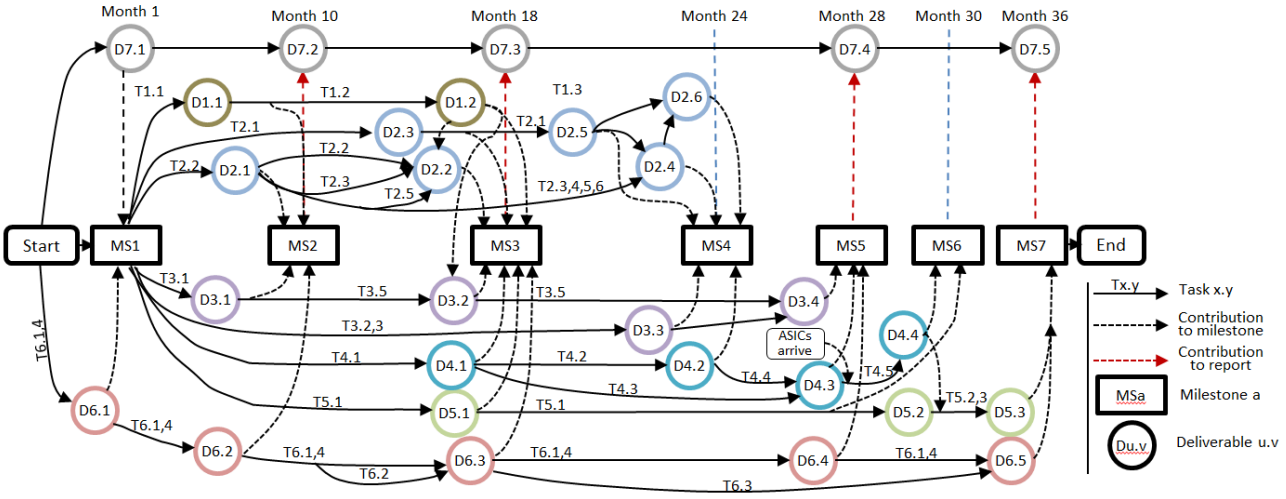


Figure 2 – Detailed Pert diagram.

3.2 Management structure, milestones and procedures

3.2.1 Organisational Structure - The **Project Management Committee** (PMC), composed by the project coordinator and the **Steering Committee** (SC), will be responsible for the coordination, daily and operational management tasks. The strategic supervision will be undertaken by the external **Advisory Board** (EAB).

The project coordinator (Prof. José Machado da Silva, UPorto) will be responsible for the overall daily management of the project concerning financial, administrative and contractual aspects. The PMC monitors project deliverables and milestones and can decide to adopt corrective measures and adapt the project's work plan if delays or deviations are detected. Progress meetings will be organized in average each nine months in order to assure full compliance with the project work plan. Project progress is monitored by the SC after compilation of the reported deliverables. Reports are communicated between participants by e-mail and through the private area of the SmarTooth web site. Providing for a future European Scientific and Industrial Leadership, the EAB in close cooperation with the PMC, will provide advices on general issues and future pathways. The PMC will meet with the EAB approximately every six months to report the project progress. The EAB will provide written assessments of the project reports which will be also delivered to the EU Commission. The EAB will be composed by three invited experts: Prof. Ana Sofia Carvalho; Prof. Gary Fedder; Dr. Marwan Abboud. CVs and specific functions are presented in section 4.3.

Table 3.2a: List of milestones

MS number	Milestone name	Related WP	Estimated date	Means of verification
MS1	Make web-page public. First dissemination activities.	WP7	M1	Web page. Fact sheet.

MS2	Biomechanics studies; Specification and preliminary validation of the first piezoelectric sensors. M1 and M2 block diagrams and energy specifications. Progress report 1.	WP1,2,3,7	M10	Report
MS3	Validation of the fabricated piezoelectric sensors. GDS files of the M1 ASIC. Antenna design and electrical characterization. Fabrication process for the 3D electrode arrays. Best battery recharging technic. Integration and packaging concept and specifications. Clinical and Ethical protocols. Dissemination material. Progress report 2.	WP1,2,3,4, 5,6,7	M18	Report, Fully operational prototypes
MS4	External controller. GDS files of the M2 ASIC blocks. Fabrication process of the electrode arrays and final prototypes. 3D electrodes and functional structures for electrochemical evaluation of the micro-batteries. SmarTooth mechanical properties.	WP1,2,3,4	M24	Report, Fully operational prototypes
MS5	Micro-battery with built-in charging circuit. Battery and chip biocompatible integration and electrical interconnection technology. Assessment of training workshop; Training material. Progress report 3.	WP3,4,6,7	M28	Report, Fully operational prototypes
MS6	Functional and electric tests of the M1 and M2 ASICs. Full system integration and SmarTooth evaluation testing. Approval of the clinical trials by the Ethical committee.	W4,5	M30	Report, Fully operational prototypes
MS7	Evaluation of SmarTooth performance. Analysis of somatosensory data. Dissemination material; Future exploitation plan: Certification process. Final report.	W5,6,7	M36	Report, Clinical data

3.2.2 Risk management – A risk assessment and management strategy will be implemented by the coordinator to define, identify and evaluate the risks that can occur during the project execution and to plan management and mitigation strategies to ensure that their impact and any deviations from the expected project results and schedule are minimised. A contingency plan will be delineated for the most severe cases. The mid-term assessment will be made against the satisfactory completion of the quantified technical / scientific targets (deliverables and milestones) established for milestones MS1, MS2, and MS3. The existence of positive and realistic perspectives for the exploitation of the results and the commitment of the partners to the objectives of the project will be a requirement for the continuation, as well. A decision whether or not to continue the contract will be then taken upon positive and realistic perspectives. The following table provides a non-exhaustive list of the potential risks the project might encounter, their impact and the proposed mitigation or contingency actions:

Table 3.2b: Critical risks for implementation

Description of risk (indicate level of likelihood: Low/ Medium/ High)	WP involved	Proposed risk-mitigation measures
Sensors performance deviation; usability limitations; reduce space for the sensor - (Medium)	WP1	Use different materials; if by month 12 it is found that piezoelectric sensors are not viable, micro capacitive sensors from Microfab will be used.
Electromagnetic interference (EMI) among various M1 and M2 modules - (Low)	WP2	Develop multiple-access scheme compatible with analog RF modulation; use new EMI shielding
Battery storage capacity is too low - (High)	WP3	Develop piezo harvesting to recharge also during the day
Power performance of battery is too low - (Medium)	WP3	Use longer recharging regime (overnight) with inductive link or infra-red harvesting
High aspect ratio battery electrode printing does not work - (Medium)	WP3	Develop alternative deposition processes (dispense, yet, electrophoretical)
Coil Q-factor, antenna gain is too low - (Medium)	WP4	Use low loss, insulator substrate and optimize battery for low RF loss, optimize component placement
Myogenic artefacts (recorded activity that is not of cerebral origin) - (Low)	WP5	Register brain and muscle activity simultaneously
Clinical trials and ethical protocol are not approved – (Low)	WP6	Perform the evaluation of the SmarTooth system using biological phantoms and a mechanical jaw
Participant leaves consortium – (Low)	WP7	Identify new participant. Redistribution of the remaining work among partners. PMC sets up regular meetings to establish and motivate communication with partners.
A partner reduces its effort – (Low)	WP7	Other partners in the Consortium (with similar level of expertise) committed to partially cover the missing contribution.
Deliverables do not meet sufficient quality standards – (Low)	WP7	Deliverables will be systematically reviewed internally early enough to allow corrections or additional work to be performed.
Underestimation of the human and material resources needed –(Low)	WP7	Effort to involve other researchers, engage more MSc and PhD students; make us of institutions own material resources.

3.2.3 Conflict resolution – Conflicts and disputes should be solved in first instance at WP level. Discrepancies in the development of the tasks must be anticipated and reported immediately to the WP leader who will try to solve them and will report every incident to the PMC. Major problems concerning technical or managerial aspects and which could not be solved otherwise, shall be addressed with the following procedures:
- Any partner may bring up a major problem. A written statement addressed to the PMC is required reporting the issue as a major problem and identifying it properly;
- First the Coordinator tries to solve the problem with the concerned member. If the major problem persists then: It will be raised at the next regular PMC meeting or calls for a special meeting to solve the problem; During that meeting, alternative solutions have to be worked out clearly; If an agreement is found among the partners the problem will be solved at this level; If not, a formal vote takes place according to PMC established procedure.

The decisions by the PMC will pursue consensus among partners. In case of vote, a weight vote might be necessary as it will be duly included in the CA of the project that will specify all the internal rules to apply for conflict resolution. The SmarTooth risk management will be based on the established project milestones and deliverables schedule. The assumed and/ or detected risks are associated with each part of the project work: project definition, scope and specification, planning, project resources, execution of the research and development work. To quantify the project risks, further to the risks listed in table 3.2.b, during the 1st month of the project a work risk log (WRL) will be defined, that consists of the following information: Risk number and risk name; Date raised; Decide the probability (Low, Medium, High); Risk status; Risk Management Form, completed (yes/ no).

3.3 Relevance of expertise in the consortium.

The SmarTooth involves an interdisciplinary team and institutions with well-known activity in relevant domains for the project. The fundamental competences needed to develop the project, i. e., dentistry and neurology (SW, GW), biophysics, microfabrication, materials and surfaces science (FBK and FHG), economics and management (GW, Triteq), microelectronics and mechanical engineering (UPorto, TUD, Triteq), marketing and regulation (Triteq, GW), are gathered in the applying consortium. Due to their more technical nature, WP1 to WP4 are those implying the higher staff effort and consequently requiring a more visible involvement of UPorto, Triteq, TUD, FHG, and FBK. All partners are involved in WP6 - Certification, Exploitation and Dissemination and WP7 - Coordination and Management. As WP5 is focused in the somatosensory evaluation of the feedback provided by the implant provided with force sensors, it is specifically conducted by neurologists and dentists (SW and GW). However, as this implies the use of the developed prototypes, the other partners will closely follow these experiments and will provide the necessary support.

UPorto has knowledge in computer mechanical and electronics and VLSI design and simulation, as well as experience with piezoelectric materials, electromagnetic radiation and propagation, small footprint ASIC design. UPorto, through its biomechanics lab (http:// / www.labiomep.up.pt/) includes facilities to perform mechanical dynamic tests.

The Bioelectronics group at **TUD** has been involved in national and international research projects that contributed to applications and products (e.g., pacemakers, hearing instruments, cochlear implants). A patent license is being negotiated with industrial partners concerning a power-efficient neurostimulator circuit principle that can be used in a variety of neurostimulators.

The Institute of Biophysics of **FBK** carries out research on biological membranes, macromolecular complexes, biomolecular imaging, and biophysical properties of natural and artificial biomembranes. In SmarTooth they will study the electrophysiological interaction between the chosen biosystems (model cells, nerve endings) and the non-biological components of the hybrid systems. FBK has already available: 1 setup for advanced patch-clamp analysis on living cells including piezoelectric micromanipulation systems; 3 setups for voltage-clamp of planar lipid membranes; and 1 semiautomatic patch-clamp system for living cells.

Fraunhofer IZM (**FHG**) holds a globally strong position in microelectronics packaging and 3D micro integration and is a leading institute for System in Package (SiP) technology. It has the capability of multi material 3D print for electronics application and embedding. The micro energy group of IZM works for more than 12 years in the development of lithium ion µbatteries and its micro integration. Special laboratories are available for electrochemical research on micro energy storage.

GadgetWhisper **(GW)** is a start-up SME with activities on development and commercialization of medical appliances and equipment for the healthcare sector. The company gathered competences on business, development of medical devices, understanding of worldwide standards for safety of medical equipment as well as experience in managing worldwide intellectual property portfolio and IP enforcement, in medicine, in dentistry and oral surgery, general management and dental implant market.

Triteq is a product design and development accredited to ISO13485 consultant company with in-house research, design, engineering, software and manufacturing capabilities. Triteq has designed and produced systems to protect infrastructure alongside safety critical medical devices that help patients and clinicians achieve information in faster time frames.

Saliwell (**SW**) has created a platform for the generation of a variety of intra-oral intelligent diagnostic and therapeutic medical appliances, non-invasive to minimally invasive, with communication to extracorporeal devices. SW has been active over 12 years in the development of intelligent intra-oral devices, mainly for electrostimulation of nerves that control salivary secretion (with CE & TGA approvals) and delivery of medications to treat chronic diseases, such as Parkinson's disease. SW holds ISO13485 certification for medical devices.

3.4 Appropriate allocation and justification of resources (person-months, equipment, budget).

The total project effort is 584 person-month for a total duration of 36 months. The effort distribution is proportional to the WP workload and to the involvement of each partner in the project, but the differences in total effort per partner cannot be taken as an indicator of higher or lower involvement in the project objectives. The effort per WP distribution is also consistent with the project objectives and the characteristics of the work to be carried out. The higher effort of UPorto results from its responsibilities in the

overall coordination and involvement in all work packages. Work packages WP2, WP3, and WP4, concentrate the highest effort, since in fact the development of the SmarTooth system requires the full-custom development of very specific and highly performant VLSI circuits, together with critical requirements of miniaturization and biocompatible packaging. All partners are actively involved in at least 4 WP, two of them being WP6 and WP7, strengthening the idea of collaborative project.

Table 3.4a: Summary of staff effort

Participant# / Short name	WP7	WP1	WP2	WP3	WP4	WP5	WP6	Total Person-months
1/ UPORTO	**24**	**25**	45	32	30	3	6	165
2/ TUD	2		**96**	2	4	1	4	108
3 / FBK	2	13	68		22	1	2	108
4 / FHG	2			**46**	24	1	1	74
5 / GW	2	7			1	8	**8**	26
6 / Triteq	2			12	**82**	1	2	99
7 / SW	2				1	**11**	1	15
Total Person-months	36	45	209	92	164	26	24	596

The total requested grant amounts to € 3,925,863 of which € 2,631,374 (67%) correspond to direct staff costs (calculated considering the different staff categories involved). Other direct costs include acquisition of secretariat consumables, electronic components and sensors, consumables for the fabrication of µbatteries and 3D electrodes, packaging of the M1 and M2 modules, boards for the demonstration electronic circuits, and costs due to dissemination, training, travelling (project progress, conferences, technical or dissemination meetings), and insurance for the volunteers involved in the trials. All partners hold already the main equipment needed to develop the respectively assigned tasks. The equipment to be acquired are laptops for the researchers, specific data acquisition boards for the pre-clinical trials, and devices for the biomechanical structure.

Other direct costs include also the fabrication of ASICs for M1 and M2 modules recurring to the EuroPractice program, the audits subcontracted to specialised companies to be conducted as per the rules of the Commission (audit certificates mandatory for EC contributions larger than 325 kEuro). The only cases where the Other costs are higher than 15% of the Staff costs are those of UPorto, GW, and SW. The following tables describe the Other direct costs of these partners. UPorto assumes higher costs also due to the coordination and management responsibilities. Most of the meetings, namely with the EAB will be made by videoconference. SW and GW include the costs incurred for the realization of the pre-clinical trials: rental of facilities, costs with the approval of the clinical and ethical protocols, expenses with the volunteers' insurance plus traveling and lodging if traveling more than 50 km. SW includes subcontracting of technical support (€15,000).

Table 3.4b: 'Other direct cost' items

1/ UPorto	**Cost (€)**	**Justification**
Travel	14,700€	Conferences: It is planned to present papers in 6 conferences (Europe) along the time frame of the project with an average of 3-4 days each Project meetings: every nine months it is planned a project meeting with three participants (1 day); steering committee meeting, one2one partner meeting, EU meeting, one participant (1day); External advisers traveling expenses.
Equipment	17,760€	Laptops, OpenBCI DAQ, valves, motors and sensors for the mechanical prototype
Other goods and services	41,760€	Other goods and services include:8.000€ consumables for the prototypes; 1200€ for auditing services; 6000€ service of the EAB; 21000€ fabrication of ASICs and mechanical parts; 600 € books; 4960€ rental of exhibition space and training room
Total	**74,220 €**	

5/ GW	**Cost (€)**	**Justification**
Travel	8,000€	Progress, test and dissemination meetings.
Equipment		
Other goods and services	50,193€	Dissemination and training material (1500€); development of web-site (2500€); Approval of the clinical and ethical protocols (3000€), Work and services, including renting hospital facilities; Volunteers compensations; Insurance: 18,193€; Goods (dental appliances): 25,000
Total	**58,193€**	

7/ SW	**Cost (€)**	**Justification**
Travel	15,000€	Progress, test and dissemination meetings.
Equipment	5,000€	Minor equipment for recording sessions
Other goods and services	118,203€	Work and services, including renting hospital facilities; Ethics Committee; Volunteers compensations; Insurance: 42,803; Goods (dental appliances): 75,400
Total	**138,203€**	

Section 4: Members of the SmarTooth consortium

4.1.1. Universidade do Porto, www.uporto.pt, (UPorto)

With origins dating back to the eighteenth century, the University of Porto is currently one the most prestigious Higher Education Institutions of Europe. Close to 32 000 students, 2 400 teachers and researchers along with 1 600 administrative staff within its 15 schools and 60 scientific research units, spread across 3 university campuses located in the city of Porto.

The Faculty of Engineering (FEUP) is the largest faculty of UPorto, with about 8 440 students and 577 teachers and researchers across 9 departments. It is located in the Asprela Campus, the main university campus in the city of Porto. In the FP7, FEUP was partner and/ or coordinator in a total of 48 projects, including as host institution of two ERC Grants. Under the new European Union Framework Programme for Research and Innovation, Horizon 2020, FEUP is already partner in 12 funded projects (Marine UAS, BRIDGES, ICI-THROUGH, IN2RAIL, HYDRALAB-PLUS, FAME, ANTAREX, HEAT-SHIELD, RISEN, PRINTCR3DIT, LIQUEFACT and PRINT-AID) and is the coordinator of 3 other funded projects (SDIN, SmartHELMET and GOTSolar). FEUP is also a third party in the EMSODEV project.

The R&D activity carried out in the FEUP and in his associated research institute INESC TEC in the biomedical engineering area addresses the domains of bioinstrumentation, biomedical imaging and neuroengineering, with projects devoted to wearable monitoring systems and embedded sensors for health, sports and well-being applications, high range of multispectral radiation image acquisition and processing, computer-aided medical diagnosis and neurophysiology and human-computer interfaces.

In the health domain, the I3S consortium, headed by the UPorto and resulting from the long-term collaboration between IBMC, INEB and IPATIMUP, encompasses joint projects focusing on the domains of cancer, host response and interaction, and neurobiology and neurologic disease.

FEUP has been collaborating actively in the last few years with the nearby dental medical faculty, being responsible for the organization of the International Conference on Biodental Engineering. By understanding the gain of this collaboration, dental medical doctors are now members of the Engineering Research Science Units of INEGI (an associated research institute of FEUP). As a result of this recent collaboration, several devices have already been developed, namely to evaluate bruxism, through the measurement of force and relative displacement between jaws, and a novel mouth guard, fully customized to fit the players' needs, stiffer and thinner than the state of art. Another important collaboration is in the construction of 3D images from medical 2D images MRI; namely to build-up models of the patient heads and maxilla to support surgery interventions, as well as face reconstruction. Relevant research is also being performed with titanium for medical application; FEUP has even a facility for die-cast complex titanium parts. Yet another research topic relevant for this project is infrared imaging actually used in several dental projects: a) to evaluate the heat produced during the cure of dental materials, b) study cancer evolution, c) evaluation of drilling tools overheat, d) muscular activity evaluation, namely on masseters, e) jaws 3D movement tracking, etc. As a result, several joint patents applications have been issued in the last 3 years.

At the Faculty of Sciences, research in applied physics is carried mainly at the IFIMUP-IN lab, who recently joined the Laboratory for Nanotechnology (INL). One line of work focuses on all types of materials: liquid crystals, dielectrics (insulators), magnetic materials and superconductors, as well as, fabrication and characterization of materials with artificial structures on the nanometer scale. The unit of Micro and Nanofabrication provides a clean room (ISO6/ ISO7) for the fabrication and characterization of micro/ nano devices and development of new structured micro/ nano materials.

The International Iberian Nanotechnology Laboratory - INL, a large international facility with 22 000 m^2 area specifically devoted to research and development in the domain of nanotechnologies is also available at Braga (a city close do Porto).

Role in the project:

In the SmarTooth project UPorto is responsible for the overall coordination and management of the consortium activities as well as for the communication towards EC officers. UPorto is also involved in all work packages serving with the knowledge and competence in the domains of, among other, sensors, biomedical instrumentation, microelectronics and VLSI design and test, RF communications, medical implants, sensor data fusion, wireless sensor networks, signal processing of biomedical data, bio-mechanics, mechanical structures modelling and simulation. UPorto is leader of WP1, related with the development and test of the pressure sensors and development of the external device to charge and control the parameters of module M2, being involved in the design and evaluation of the ASICs for modules 1 and 2 and in the charger for the micro-batteries, as well. UPorto will supervise the development of the data acquisition equipment to be used by GW to carry out the pre-clinical trials.

Profile of staff members

- **José Machado da Silva (Male)**

José Machado da Silva (www.fe.up.pt/~jms/index.html) obtained a PhD degree in Electrical and Computer Engineering in 1998 at the Faculty of Engineering of the University of Porto (FEUP), Portugal. He is currently an Associate Professor at FEUP with the Department of Electrical and Computer Engineering and a Research Manager and Project Leader in the Center of Telecommunications and Multimedia of INESC TEC. He is also director of the Master programme in Biomedical Engineering and Deputy Director of the Integrated Master in Bioengineering. His teaching and research interests include analogue, mixed-signal RF and electronics, VLSI design and test, signal processing, and instrumentation for biomedical applications. He was the Principal Investigator of the projects in the domain of biomedical engineering SIVIC, ProLimb, and coordinator of the participation of UP in project SensecardioHealth. He was also coordinator of the participation of INESC TEC in the European projects ELESIS (ENIAC programme, 2012-2015); TOETS (CATRENE/EUREKA, 2009-2012); ACEOLE (CERN – Marie Curie Initial Training Networks, 2008-2011); NanoTEST (MEDEA+, 2005-2007); DYNAD (SMT4-CT98-2214, 1998-2001). He co-editor of one book, co-author of three book chapters, published more than 100 papers in international journals and proceedings with peer review, and is co-author of one patent. He supervised or supervises 5 PhD students and more than 20 MSc students.

- **Joaquim Gabriel (Male)**

Joaquim Gabriel is with the Automation, Instrumentation and Control group, Department of Mechanical Engineering, Faculty of Engineering, University of Porto. He is currently an Assistant Professor at FEUP. He is also researcher at INEGI (Institute of Mechanical Engineering and Industrial Management) which belongs to the Associated Laboratory LAETA one of the Portuguese high rank laboratories. He received the degree in Mechanical Engineering, specialization on Machine Design and a post-graduation in Automation and Management of Industrial Processes from University of Porto; he holds a Master from University of Porto in Industrial Computing and a PhD from the University of Minho in Industrial Electronics. He was research fellow of JNICT (Portuguese Research Foundation) at University of Porto (1989), and was researcher from the Japanese Ministry of Industry at Science Park in Kanagawa, Japan (1995-97). He is currently member of the National Engineering Association, IEEE (Instrumentation and Measurement Society), International Association of Science and Technology for Development, International Federation of Automatic Control and European Association of Thermology. He is currently responsible for a research group at FEUP in healthcare and is advisor / co- advisor of 16 PhD students in the areas of medicine and engineering. Joaquim Gabriel is author/ co-author of 3 books, 6 book chapters, and editor 5 of books, 40 articles in international journals, 9 in national journals, 165 papers in proceedings of conferences, 10 patents and 30 awards. He was coordinator (or part of the research team) of 9 international and 37 national projects.

- **Octavian Adrian Postolache (Male).**

Octavian Adrian Postolache is principal researcher of Instittuto de Telecomunicações, Leader of Instrumentation and Measurement group of IT-IUL and leader of Sensing and Pervasive Computing Laboratory as part of Instrumentation and Measurement Group. He is also professor of School of Architecture and Information Technologic, Instituto Universitário de Lisboa, Portugal.

His fields of interests are smart sensors and distributed instrumentation for environmental monitoring and biomedical measurements, sensor data fusion, wireless sensor networks, signal processing of biomedical data for health status and instrumental activity estimation, computational intelligence with application in automated measurement systems. He is currently leader of project regarding the implementation of Electronic Health Records for Physiotherapy (EHR-Physio). He worked as a board member of Institute of Telecommunications – Portuguese Telecommunication Agency for Innovation (PT Inovação) - Home TeleCare project; and Institute of Telecommunications and National Communication Agency (ANACOM) - Integrated Spectrum Monitoring project.

Octavian Postolache is author and co-author of 9 patents, 7 books, 16 book chapters, more than 305 papers in international journals and proceedings with peer review. He is IEEE Senior Member I&M Society and he is chair of IEEE I&M TC-13 committee on Wireless and Telecommunications in Measurements, IEEE I&M Portugal Chapter Chair. He is associate editor of IEEE Sensors Journal, IEEE Transactions in Instrumentation and Measurement, Guest Editor of Sensors.

Publications:

- Cristina C. Oliveira, José Machado da Silva, "Fault diagnosis in highly dependable medical wearable systems", accepted for publication in the Journal of Electronic Testing - Theory and Applications, 2016.

- Oliveira, C.C.; Sepulveda, A.T.; Almeida, N.; Wardle, B.L.; Machado da Silva, J.; Rocha, L.A., "Implantable Flexible Pressure Measurement System Based on Inductive Coupling," Biomedical Engineering, IEEE Transactions on, vol.62, no.2, pp.680,687, Feb. 2015.
- Antonio José Salazar Escobar, José Machado da Silva, Miguel Correia, Bruno José Mendes, "Built-In Self-Testing Methodology and Infrastructure for an EMG Monitoring Sensor Module", IARIA International Journal On Advances in Systems and Measurements, Vol. 7, No. 1&2, 2014.
- M.R Ribeiro; Postolache, O.; Girão, P.M.; "A Novel Smart Sensing Platform for Vital Signs and Motor Activity Monitoring" - Chapter in Sensing Technology: Current Status and Future Trends I, Mason, A.; Mukhopadhyay, S.C.; Jayasundera, K.P.; N. Bhattacharyya, Springer, Heidelberg, 2014.
- Joaquim Gabriel, PhD Thesis "Two Novel Piezo-Actuations: an Accurate Micropositioning Device and an Active Vibration System for Sewing Machines", Universidade do Minho, 2003.

Relevant Projects:
The PI is (or was) coordinator of/ or researcher in the following projects

- CREATION Cognitive Radio Transceiver Design for Energy Efficient Data Transmission, EXCL/ EEI-TEL/ 0067/ 2012
- SIVIC Wearable Integrated Cardiovascular Surveillance System, PTDC/ EEI-ELC/ 1838/ 2012, project coordinator.
- ENIAC ELESIS "European Library-based flow of Embedded Silicon test Instrument", European Program, from 2012 to 2015 http:// www.eniac.org/ , coordinator of the Portuguese participation.
- ProLimb - Electronic Sensing for the Prophylaxis of Lower Limb Pathologies, PTDC/ EEA-ELC/ 103683/ 2008, project coordinator
- SenseCardioHealth, MIT-Pt/ EDAM-EMD/ 0007/ 2008, coordinator of FEUP participation

Available infrastructure &equipment
UPorto provides networking facilities, access to a parallel computer cluster for heavy simulations, scientific software (Fluent, Abaqus, Ansys, Solid Works, Matlab, LabVIEW,…), and specialized labs: Biomechanical Lab, Casting, Composite Material Lab, Clean room, Rapid Prototyping Lab, Virtual Serious Games Lab, Warehouse, and VLSI design and simulation tools. Fully equipped laboratories (e.g., network and spectrum analysers, various dc and signal and logic generators and analyzers, and facilities for fabricate simple PCBs) are available at UPorto. The clean room of the Faculty of Sciences provides means to perform piezo materials deposition. The Biomechanical Lab of UPorto makes available a dynamic press for the implant validation tests and video motion tracking system.

4.1.2. Technische Universiteit Delft, http:/ / www.tudelft.nl/ en, (TUD)

Delft University of Technology is a modern university with a rich tradition. Founded in 1842, Delft University of Technology is the oldest, largest, and most comprehensive technical university in the Netherlands. Its eight faculties are among the topmost of technological development, contributing to scientific advancement in the interests of society. Ranked among the top universities of technology in the world TU Delft's excellent research and education standards are backed by outstanding facilities, research institutes and research schools. TU Delft recognizes valorisation of knowledge as an important part of its strategy and maintains close links with (inter)national industry, a strategic alliance beneficial for the relevance of its research, academic programmes and career prospects for its graduates. All educational programmes encourage creative and independent thinking and focus on problem solving. The student body is comprised of about a hundred nationalities. The university has partnerships with more than thirty leading universities all over the world, enabling students and researchers to increase their international experience through cooperation and exchange.
TU Delft recognizes health as one of today's major social issues. Finding the right solutions is vital to our prosperity and welfare, and also affords promising economic opportunities. TU Delft acts as an expert partner for companies and government agencies working on these issues. TU Delft supplies independent knowledge and driven engineers. Advanced scientific research and education, together with academic inquisitiveness, provide new insights and innovations. This makes the university an expert and above all, an inspiring partner in consulting or project-based alliances.
The involvement of TU Delft in SmarTooth is through the activities of its Bio-Electronics Section.
The mission of the Bio-Electronics Section is to provide the technology for the successful monitoring, diagnosis and treatment of cortical, neural, cardiac and muscular disorders by means of electroceuticals. To

this end the lab conducts research on, provides education in and helps creating new businesses in neuroprosthetics, implantable electronics, flexible implants, microsystem fabrication, biosignal conditioning / detection, transcutaneous wireless communication, power management, energy harvesting and bioinspired circuits and systems.

Role in the project:
In SmarTooth, TU Delft will lead WP2, providing cutting-edge neurostimulator, sensory data acquisition, reactive near-field transmitter, receiver and energy harvesting units on two integrated circuits for the two implantable modules. The expertise of the Section Bio- Electronics of TU Delft is well founded and internationally recognized. TU Delft will also be strongly involved in WP3 of the project.

TUD: Profile of staff members
- Wouter A. Serdijn (Male)
Wouter A. Serdijn is full professor and the head of the Section Bioelectronics of TU Delft (TUD- BE). He received the M.Sc. (cum laude) and Ph.D. degrees from Delft University of Technology, Delft, The Netherlands, in 1989 and 1994, respectively.
His research interests include low-voltage, ultra-low-power and ultra-wideband integrated circuits and systems for biosignal conditioning and detection, neuroprosthetics, transcutaneous wireless communication, power management and energy harvesting as applied in, e.g., hearing instruments, cardiac pacemakers, cochlear implants, neurostimulators, portable, wearable, implantable and injectable medical devices and electroceuticals.
In the above domain he edited and authored 9 books, 8 book chapters and more than 300 scientific publications and presentations. He has supervised or is supervising 30 PhD students and 103 MSc students. He received the Electrical Engineering Best Teacher Award in 2001, 2004 and 2015.
In 2011, Wouter A. Serdijn has been elevated to IEEE Fellow, the highest member grade within the IEEE, for his contributions to integrated circuits for medical devices and wireless communications, and is currently an IEEE Distinguished Lecturer and a mentor of the IEEE. In 2016 he received the IEEE Circuits and Systems Meritorious Service Award. Prof. Serdijn will be primarily responsible for the research tasks within WP2.

Publications:

- Marijn van Dongen and Wouter Serdijn: Design of Efficient and Safe Neural Stimulators – a multidisciplinary approach, Springer, 2016,ISBN 978-3-319-28129-2, DOI 10.1007/ 978-3-319-28131-5.
- Andre L. Mansano, Yongjia Li and Wouter A. Serdijn: An Autonomous Wireless Sensor Node With Asynchronous ECG Monitoring in 0.18 um CMOS, IEEE Transactions on Biomedical Circuits and Systems, Digital Object Identifier 10.1109/ TBCAS.2015.2495272.
- Mark Stoopman, Yao Liu, Hubregt J. Visser, Kathleen Philips and Wouter A. Serdijn: Co-Design of Electrically-Short Antenna-Electronics Interfaces in the Receiving Mode, IEEE Transactions on Circuits and Systems II: Express Briefs, DOI 10.1109/ TCSII.2015.2406371.
- Marijn N. van Dongen and Wouter A. Serdijn: A Power-Efficient Multichannel Neural Stimulator Using High-Frequency Pulsed Excitation From an Unfiltered Dynamic Supply, IEEE Transactions on Biomedical Circuits and Systems, DOI: 10.1109/ TBCAS.2014.2363736.
- Mark Stoopman, Shady Keyrouz, Hubregt J. Visser, Kathleen Philips and Wouter A. Serdijn: Co-Design of a CMOS Rectifier and Small Loop Antenna for Highly Sensitive RF Energy Harvesters, IEEE Journal of Solid-State Circuits, Vol. 49, No. 3, March 2014, pp. 622-634, DOI 10.1109/ JSSC.2014.2302793.

Previous projects & activities:
TUD-BE has been involved in number of research projects that have contributed to applications and products (e.g., pacemakers, hearing instruments, cochlear implants), both under the Dutch Technology Foundation (STW) umbrella and under other research contracts. Currently, a patent license is being negotiated with industrial partners concerning a power-efficient neurostimulator circuit principle that can be used in a variety of neurostimulators.
TUD-BE is currently participating in the "MASSIVE -- Autonomous Vital Signs Monitoring" research program that is supported by CNPq, CAPES, CSC and Delft University of Technology. In this program, we work on the development of sensors that wirelessly receive power and wirelessly transmit vital signs like body temperature, electrocardiogram, electromyogram and electroencephalogram.

TUD-BE is currently participating in the "SINs -- Smart Implantable Neuro-stimulators" research program, that is a collaboration of Delft University of Technology (4 sections, 3 departments), Erasmus University

Rotterdam, Dunedin School of Medicine, Otago University, University of Texas at Dallas, the Brain Research Center for Advanced, Innovative and Interdisciplinary Neuro-modulation and Irion Technologies. In SINs, we work on research and development of electroceuticals for research on and treatment of a multitude of brain disorders, i.e., tinnitus and addiction.

TUD-BE is currently participating in the Dutch Technology Foundation (STW) project (11693) "REASONS – Real-time Sensing of Neural Signals", in the Netherlands. This project targets the development of a completely new readout system for measuring the so called electrically evoked compound action potential (eCAP) coming from the auditory nerve. To develop this readout system, new electronic circuitry will be designed based on state of the art technologies integrated with the electrode itself. Existing systems will be tested extensively to develop novel measurement algorithms for the new readout system. Animal experiments will be performed on existing and new readout systems. We expect to come up with circuits and systems for reading out neural responses that offer more functionality, better performance and enjoy drastically reduced form factor and power consumption. Clinically, the neural response will give new insight in the potential of eCAP recordings and take the first step in moving toward fitting to the patient without subjective data. Future patients will be rehabilitated better and faster with the newly developed methods.

TUD-BE participated in the STW project (DTC.6418) "BioSens – Biomedical Signal Processing Platform for Low-Power Real Time Sensing of Cardiac Signals" , in the Netherlands. This project, by means of i) the mathematical modeling of cardiac signals and pathologies, ii) the design of WT-based algorithms for intelligent sensing and feature extraction, and iii) the development of low-power analog integrated circuits that implement the required wavelet transform and artifact detection, taking into account the limitations imposed by an implantable device, produced, apart from publications and patents, the materialization of the scientific research efforts into validated prototypes of pacemaker and implantable cardio defibrillator front-ends. The project's primary was Medtronic. Other users of the project were: Vitatron, Maastricht Instruments, SystematIC Design, Weijand R&D Consultancy and Twente Medical Systems International.

Available infrastructure & equipment
All equipment necessary (e.g., an automated wafer probing station, various dc and signal and logic generators and analyzers, ultra-low frequency, ultra-low power and ultra-low noise measurement equipment and everything to bond, "flip chip" and package the ICs and to create PCBs) is already available at TU Delft.

4.1.3. Fondazione Bruno Kessler, http:/ / www.fbk.eu/ , (FBK)

FBK has nearly thirty years of research activities in the fields of information technology, micro-systems, and physical chemistry of surfaces and interfaces. Its Materials and Microsystems Centre (CMM) focuses research on key areas of materials and microsystems for applications in life sciences, sustainable energy and sensors development. CMM laboratories are fully equipped with Microfabrication Laboratories class 10 to 1000 and a Micro Nano Analytical Laboratory which is equipped with analytical techniques for morphological, spectroscopic and structural characterization. In this proposal the interdisciplinary expertise on biophysics, bionanotechnology and bioimaging of the Laboratory of Biomolecular Sequence and Structure Analysis for Health (FBK-LaBSSAH) is also involved. This is a laboratory with the aim to integrate biology, physics, chemistry, informatics and engineering for the future of the biomedical technologies. LaBSSAH instrumentation comprises: 1) molecular and cell biology instrumentation (chromatography, nucleic acid and protein gel electrophoresis/ blotting setups, digital systems for gel analysis, oligopeptides synthesizer, ultracentrifuge, real time and conventional PCR thermal cyclers, vacuum concentrator, sonicator, spotter); 2) characterization instruments: optical spectroscopy (absorbance and fluorescence), fluorescence microscopies (wide field and confocal), SEM microscopy, AFM, FTIR, light scattering and XPS; 3) the NGS facility, shared with the CIBIO center of the Trento University, equipped with the HiSeq2500 and MiSeq Illumina sequencers, ION Torrent PGM from Life Technologies and laboratory devoted to NGS library preparation.

Role in the project:
In SmarTooth, FBK major effort is focused on the development of the biocompatible microelectrodes in WP2 but other activities are also planned in WP1 and WP4, providing respectively the fabrication of the miniaturized force sensors and the study and realization of biocompatible packaging. The senior researchers involved in the project have a long experience in their own research fields and through the SmartTooth consortium they have the opportunity to share and use their competences in the specific field

of neurophysiology and dentistry.

FBK: Profile of staff members

- **Cecilia Pederzolli (Female)**

Cecilia Pederzolli is team leader of the FBK Biofunctional Surfaces and Interfaces research group (BioSInt) and manging director of the Biomolecular Sequence and Structure Analysis for Health (LaBSSAH). Her interest is the development of biofunctional materials applied to the micro-nanotechnologies for genomics and proteomics; she spent the last 10 years in the development of microdevices for molecular diagnostic.
Her own research activity has been focused on the following themes: 1) spectroscopic techniques for the study of bacterial toxins as transmembrane proteins; 2) immunolysins and lytic peptides in oncological treatments; 3) drug delivery systems for oncological applications; 4) development of biointerfaces for biosensors and biomedical applications. She graduated in Biology at the University of Padova, since then she worked in the biochemical and biophysical fields first at the Department of Physics of the University of Trento and subsequently in the area of Surface Science at the FBK. She coordinated several projects, citing one of the recent - "A Nano on Micro approach to a multispectral analysis system for protein assays", Autonomous Province of Trento (PAT) Grandi Progetti 2008-2012 (budget 3 Meuro), and she is responsible scientist for FBK within other projects: project NEWTON - Advanced nanosystems for a new era in molecular oncology, MIUR-FIRB 2011-2016 (budget 0.7 Meuro); project MaDEleNA - Developing and Studying novel intelligent nanoMaterials and Devices towards Adaptive Electronics and Neuroscience Applications, PAT Grandi Progetti 2012-2016 (budget 0.2 Meuro); project AXONOMICS – Identifying the translational networks altered in motor neuron diseases, PAT Grandi Progetti 2012-2016 (budget 0.4 Meuro). She has published about 200 papers on international JCR journals and presentations at conferences.

- **Leandro Lorenzelli (Male)**

Received the Laurea degree in Electronic Engineering at the University of Genova in 1994 and a PhD in 1998 in Electronics Materials and Technologies at University of Trento. During the Ph.D. his research was focused on the development of CMOS-based electrochemical microsensors. Since 1998 he joined the staff of the ITC-irst Microsystems Division (now FBK-CMM Bruno Kessler Foundation – Centre for Materials and Microsystems) and he was involved in the realisation of microsystems for biomedical, environmental and agro-food applications.
Since 2005 he is head, at FBK-CMM, for the BioMEMS research area. His main scientific interests are in the microfabrication technologies for both BioMEMS and microtransducers. During his appointment, several research projects have been initiated including: microsystems for toxicological analyses, microsystems for neuron electrical activity monitoring, DNA sensors and microfluidics for microseparation systems.
Currently, he is coordinator of the European projects on the area of flexible electronics (ITN Marie Curie Project CONTEST) and on the field of microsystems for food quality control (EU STREP Project SYMPHONY).
His main research interests are addressed on technologies for hybrid (polymer-solid state) sensors, soft-MEMS, lab on chip for agrofood applications and flexible devices.
Since 2013 is coordinator of the Microsystems Technology (MST) research unit at FBK.

- **Carlo Musio (Male)**

EXPERTISE AREAS. Biophysics and Physiology of Sensory Systems; Visual Neurosciences; Photosensory Biophysics; Photoreception and Phototransduction; Neurobiophysics; Neurobiology of invertebrates; Invertebrate Experimental Systems in Neurobiology. FORMATION AND PROFESSIONAL TITLES. CM received the Laurea degree in Biological Sciences (with neurophysiological address) from the University of Pisa at the Dept. of Animal and Human Behavioral Sciences (currently Dept of Biology), working on the neuronal basis of behavior in Aplysia. Being awarded a CNR Research Fellowship in Biophysics for two years, he moved to the CNR Institute of Cybernetics "Eduardo Caianiello" (ICIB-CNR), Naples, at the Neurosystems Group, belonging to the Neuroscience Dept. early founded by Prof. V. Braitenberg, to carry out researches on Hydra photoreception. From 1994 to 2011 at ICIB-CNR he got tenured positions until the permanent one as CNR Research Scientist which he holds nowadays. Within CNR (Italian National Research Council) he has covered several responsibility positions, e.g. Principal Investigator, Resarch Unit Responsible. On 2011 he moved to the CNR Institute of Biophysics, Unit of Trento (IBF-CNR), to establish a research project on photosensory biophysics and electrophysiology of neurosystems. At IBF-CNR he is currently PI of the "Photosensory and Neurosystemic Biophysics Lab" and responsible of the Unit afferent to the PAT-Project MaDEleNA. PUBLICATIONS. Over fifty peer-reviewed papers in international journals and proceedings of photobiology and neurosciences, CM edited four books with World Scientific Publishing and one book with Springer Verlag, and a special issue of the journal Brain Research (Elsevier).

He contributed with a chapter to the authoritative "Handbook of Organic Photochemistry and Photobiology, 3rd ed., 2012, CRC Press".

Publications:

- Juarez-Hernandez, L. J.; Cornella, N.; Pasquardini, L.; Battistoni, S.; Vidalino, L.; Vanzetti, L.; Caponi, S.; Serra, M. D.; Iannotta, S.; Pederzolli, C.; Macchi, P. & Musio, C. (2016), "Bio-hybrid interfaces to study neuromorphic functionalities: New multidisciplinary evidences of cell viability on poly (anyline)(PANI), a semiconductor polymer with memristive properties" Biophysical chemistry 208, 40-47
- Potrich, C.; Vaghi, V.; Lunelli, L.; Pasquardini, L.; Santini, G.; Ottone, C.; Quaglio, M.; Cocuzza, M.; Pirri, C.; Ferracin, M.; Negrini, M.; Tiberio, P.; Sanctis, V. D.; Bertorelli, R. & Pederzolli, C. (2014), "OncomiR detection in circulating body fluids: a PDMS microdevice perspective", LAB ON A CHIP 14, 4067-4075.
- Fiorilli, S.; Rivolo, P.; Descrovi, E.; Ricciardi, C.; Pasquardini, L.; Lunelli, L.; Vanzetti, L.; Pederzolli, C.; Onida, B. & Garrone, E. (2008), "Vapour-phase self-assembled monolayers of aminosilane on silicon substrates", Journal of Colloid and Interface Science 321, 235-241.

4.1.4. Fraunhofer IZM, http:/ / www.izm.fraunhofer.de/ en.html (FHG)

Fraunhofer IZM it holds a globally strong position in microelectronics packaging and 3D micro integration. IZM has been involved in numerous EU projects (e.g. muFly, NANOTEC, PASTA) and is coordinator of LCA-TO-GO (265096), PHOXTROT and MATFLEXEND (604093). It has over 2000 m2 clean room facility for Wafer level packaging, high density interconnect printed circuit board and micro battery technology.

Relevant skills/ experience/ technologies
In 2009 IZM presented the first full functional 3D printed electronic demonstrator at VRAP Leiria. IZM is a leading institute for System in Package (SiP) technology. It has the capability of multi material 3D print for electronics application and electronic module embedding. The micro energy group of IZM works for more than 12 years in the development of lithium ion micro batteries and its micro integration. Special laboratories are available for electrochemical research on micro energy storage. Advanced test facilities for materials research among others are nano CT and highest depth / resolution FIB, advanced rheometers. Large experience is related to topics like screen print and jetting of solders and electrical connections, micro molding, transfer moulding, underfill and embedding of electronic components. Fraunhofer IZM uses 3D print and rapid prototyping technologies for more than 10 years to develop micro packages and housings for MEMS, medical and automotive electronics.

Role in the project
IZM will lead WP3 the power supply development for medical applications. The work will be focussed on paste development and rheology adaption for battery electrodes and separators, on technology development of 3D jet deposition for electrochemically active masses which are required for a novel micro battery integration concept. In WP4 IZM will develop the packaging and integration of the multifunctional implantable electronic module with extreme miniaturization together with FBK.
IZM will actively promote the integrated micro battery technology and play an active part in dissemination and exploitation of that technology (WP6)

FHG: Profile of staff members

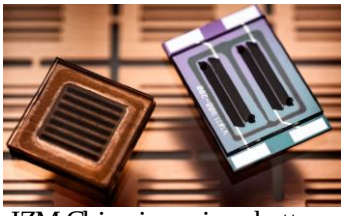
- **Robert Hahn (Male)**
Received the Ph.D. degree in electrical engineering from the Technical University of Dresden, Germany, in 1990. Since 1994 he is with the Fraunhofer IZM where he is head of the micro energy group. He has taken over the coordination of several research projects for the development of new batteries, and integrated power supplies and miniaturized packages. Dr. Hahn has authored and co-authored more than 100 papers in the fields of microelectronics packaging and energy systems as well as 30 patents in the area of micro energy systems. He is a lecturer at TU Berlin for micro energy and energy harvesting and coordinator of the FP7 project MATFLEXEND.

- **Ms. Marion Henriette Molnar (Female)**

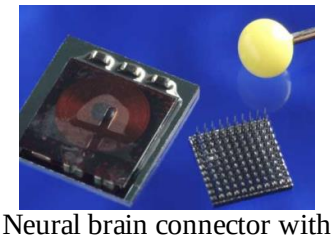
Received the MS degree in regenerative energy systems at TU Berlin in 2013. She obtained a BS degree in process engineering at TU Berlin in 2011 and in Physics at Humboldt University in 2009. She is member of the work group Micro Energy Storage of Fraunhofer IZM since 2014. Her research focus is on metal and laminate technology for packaging of integrated rechargeable batteries and materials compatibility testing.

- Prof. Dr. -Ing. Dr. sc. techn. Klaus-Dieter Lang; (Male); PhD;
Studied Electrical Engineering from 1976 to 1981 at Humboldt University in Berlin. Since February 2010 he is Director of the institute and responsible for the chair "Nano Inter-connect Technologies" at Technical University Berlin. Prof. Lang is member of numerous scientific boards and conference committees. Examples are the SEMI Award Committee, the Scientific Advisory Board of EURIPIDES, the Executive Board of VDE-GMM and the scientific chair of the Conference "Technologies of Printed Circuit Boards" He is the author and co-author of 3 books and more than 130 publications in the field of microelectronic packaging, microsystems technologies, and others.

Relevant Research projects
In FP7 MATFLEXEND (604093) (2013-2015) IZM develops printable battery electrodes and separators for flexible batteries and energy harvesting systems.
In MikroLib (Fraunhofer 2011-2015) IZM leads the Fraunhofer activity for integrated micro batteries for silicon and ceramic integration. In AlSiBat (BMBF 2014-2017) IZM develops the micro integration and testing of metal air micro batteries. In BattPlas (BMBF 13N8861- 13N8864) IZM developed the bio compatible and saliva resistant micro battery package for first electronic tooth implants. IZM has a more than 10 years cooperation with the university of Utah for development of the electronics packaging of brain implanted neural recording and stimulating devices.


IZM Chip size micro battery


Electronic tooth implant


Neural brain connector with inductive interface

Existing infrastructure

- In 2016 a 10 meters long argon glove box line was implemented dedicated to the prototype fabrication of micro batteries. Integrated 3D printer and jetting and dispensing robots will allow prototype manufacturing of integrated micro batteries to be developed in SmarTooth. A special electrolyte filling adapter is designed for simultaneous filling of hundreds of micro batteries on the same substrate.
- Numerous materials characterization methods are available at the institute like SEM, EDX, MicroDAC, NanoDAC, XPS, AFM/ SFM, spectroscopic methods like UV/ vis, nano CT (phoenix nanotom) and highest depth/ resolution FIB (FEI Heloios NanoLab 600i).
- For battery research complete electrochemical laboratories with more than 340 test channels for lithium batteries in climatic chambers, potentiostats, electrochemical quartz crystal micro balance, impedances spectroscopy are available.
- Three roll mills, speed mixers ultrasonic stirrers and advanced rheometers are used for paste and slurry development.


Micro battery prototyping line

Relevant publications/ patents/ products/ services/ Papers

• Frank Ansorge, Katja Heumann, David Ifland, Herbert Reichl, "Embedding of electronic and system in package using generative processes", in Advanced Research in Virtual and Rapid Prototyping, Paulo Jorge

Bartolo et al. (Editor), CRC Press 2010, ISBN 9781439859216

- R. Hahn, K. Höppner, M. Ferch, K. Marquardt, K.-D. Lang, "Direct integration of lithium micro batteries for highly miniaturized electronic systems", IDTechEx Energy harvesting and storage Europe, Berlin, 1.-2. April 2014
- Robert Hahn, Leopold Georgi, Priscila Ertmann Bolzan, Yujia Yang, Uwe Maaß, Jörg Bauer, Merlin Bergmeister, Jonas Strobelt, Felix Krause, Rene Dallinger, „A noel capacitive energy harvesting concept" IDTechEx Energy Harvesting and Storage Europe 2015, Berlin 28.-29. April 2015
- K. Hoeppner, M. Ferch, K. Marquardt, R. Hahn, B. Mukhopadhyay, et al. „Silicon-integrated secondary Li-ion micro batteries with side-by-side electrodes for the application as buffers in self-sufficient energy harvesting micro systems", 225th ECS Meeting, May 11-15 201, Orlando
- R. Hahn, K. Höppner, M. Ferch, K. Marquardt, K.-D. Lang, , Development of Integrated Lithium Ion Micro Batteries, in Microelectronics Packaging in the 21th Century, Chapter VIII, pp. 392-399, Fraunhofer Verlag 2014, ISBN: 978-3-8396-0826-5

Patents

6) Integrated Micro battery EP 1 673 834 B1, US 8,003,244 B2, DE 103 46 310.0-45
7) Micro battery electrolyte filling DE 10 2007 012 693.1
8) 3D micro battery, DE 10 2008 011 523.1, US2011070480A, US 12/ 919,539
9) Hermetic encapsulation of micro battery, DE102010036217
10) Producing 3D parts with help of fusible material and generative process, DE102013007059

www.matflexend.eu
www.izm.fraunhofer.de/ de/ news_events/ events/ workshop-micro-battery--and-capacitive-energy-harvesting.html
www.smart-power.de

4.1.5. GadgetWhisper (GW)

The GadgetWhisper is a start-up SME company that has gather 1.5 Million Euros in Matching Fund Commitments from VC Funds, and develops its activities in the Healthcare Sector within the Medical Appliances and Equipment, by developing and commercialization of medical devices. The first product will be an Active Implantable Medical Device focused on restoring dental sensitivity for people that have dental implants (SmarTooth).

Vision/ Mission

Our Vision is to restore the wellbeing and health of people that have lost their teeth, and to achieve this we have a Mission to provide a state of the art medical device that will restore dental sensitivity, taking a huge step by transforming current dental implants into active prosthesis that are very close to the human teeth.

Objectives

The main goal is to reach the market with a revolutionary product that will be adopted by the dentist community, becoming the state of the art in complementing dental prosthesis.

Team members

The initial structure of the company was created taking in account the amount of workload and expertise needed during the 3 initial years of the SmarTooth project. Accordantly to our business plan the Human Resources number will reach 15 members during the stage of market pilot validation.

The company has a team with knowledge on senior engineering management experience, business development and extensive hands-on experience with engineering functions and development of medical devices, extensive understanding of worldwide standards for safety of medical equipment as well as experience in managing worldwide intellectual property portfolio and worldwide IP enforcement, in medicine, in dentistry and oral surgery, general management and dental implant market.

The GadgetWhisper team demonstrated the capability during the last 3 years to create state of the art concepts in the medical area form a solid and prestige networking of key players in different fields (including industry, opinion leaders, research institutions and capital risk funds) and prepare the viability and sustainability of the project after the Horizon 2020.

Role in the project:
Study of biomechanics phenomena (forces exerted on teeth) in WP1, specifications for design, packaging and interconnection (WP4), neurophysiologic and evoked somatosensory feedback tests (WP5), IP management, market and VC Funds relations and contacts, establish further networking and perform exploitation and dissemination of the SmarTooth (WP6), support project coordination during the Horizon 2020 period and follow all the activities within (WP7)

GW: Profile of staff members

- **Jorge Marinho (Male).**

Jorge Marinho, MD, PhD, the inventor of the SmarTooth concept, graduated in Medicine and Surgery at the Institute of Biomedical Sciences Abel Salazar (University of Porto), held the general internship at General Hospital Santo Antonio in Porto. He specialized in stomatology with competence in Maxillo-Facial Surgery at the Department of Stomatology and Maxillo- Facial Surgery, St. John's Hospital in Porto. Co-author of the new solution concept for obtaining dental 3D models for implant prosthodontics. Co-author of a new universal dental abutment.

- Assistant Hospital of Stomatology of the Portuguese Institute of Oncology of Porto. Master in Clinical Pathophysiology at the University of Navarra - Spain. Is Doctor of Stomatology at the University of Santiago de Compostela – Spain.
- Responsible for the sector and Prosthetic Surgery Maxillo- Facial Rehabilitation in Stomatology Department, Department of Surgical Oncology , the Portuguese Institute of Oncology of Porto.
- More than 25 000 patients seen and treated in Oncology Rehabilitation and Maxillo-Facial and over 6000 dental implants placed.
- 2 Praises of merit in clinical performance (1988 Independent Mixed Brigade NATO and 2008 the Regional Health Administration of Northern Portugal).
- Co-founder in 2006 of the Portuguese Association of Hospital Dental Medicine and was its first President.
- Between 1986 and 1999, Led ER (Emergency Room or Department) in 4 district hospitals in Northern Portugal.
- Between 1986 and 1992 joined the team of weekly urgency of the S John Central Hospital on Plastic and Reconstructive Surgery, and participated in about 220 surgeries with the technique of pedicle and vascular microsurgery.
- Author of 6 scientific articles in international journals, and a medical device patent. Speaker at conferences, congresses and scientific meetings in Portugal, Brazil, Spain, Germany, Sweden, Canada and the USA.

- **João Vasconcelos (Male)**

João Vasconcelos, has a Dental Science Degree and an Business Administration degree from University of Porto (attended 3 years in University of Washington). Specialization in Physiology and Pathophysiology by the Faculty of Medicine, University of Porto. Specialized in marketing technologies by COTEC (Portuguese Business Association for Innovation). Co-author of the new solution concept for obtaining dental 3D models for implant prosthodontics. Co-author of a new universal dental abutment. Has extensive professional experience in managing day-to-day activities, strategic business planning and project management.

Most Relevant Professional Experience:

- Clinica Médica ST. António de Joane, as a Chief Operating Officer 2006-present
- Manage day-to-day activities and oversees 42 associates in this small group, specialized in Dental Health Services; Responsible for strategic business planning, new services development and market prospecting
- Portuguese Red Cross, 2014-present, Coordinator of the commission that is developing the Red Cross Health and Social Cluster in northern Portugal
- Oporto Holy House of Mercy, Adviser to the Chairman/ CEO and Head of the Department of Planning, Project Management and Strategy, 2002-2006; Served as a special assistant and adviser to the Chairman/ CEO of this 5 Billion Euros Institution and oversaw the department of planning, project management and strategy.
- Performed strategic analysis and developed new business units and partnerships.

- Project leader in the 860 Million Euros Public Private Partnership (PPP/ PFI) to build and manage "Hospital of Loures".
- Project leader and implemented several healthcare and social care facilities such as hospitals, ambulatory units and nursing homes for the elderly.
- Project leader and implemented the first Portuguese Public Private Partnership to manage a Prison Facility and served as a member of the Board of this establishment.

Publications:

- A novel concept in implant utility, Marinho, Jorge et al. European Archives of Othorino Laryngology and Head & Neck Vol 267, pp. 053, March 2010.
- A new surgical approach to reduce anchyloglossia after oncology surgery, Marinho, Jorge et al. European Archives of Othorino Laryngology and Head & Neck Vol 267, pp. 030, March 2010.
- Changes in salivary composition in patients with renal failure Tomás I1, Marinho JS, Limeres J, Santos MJ, Araújo L, Diz P. Arch Oral Biol. 2008 Jun;53(6):528- 32.
- Oral health status in patients with moderate-severe and terminal renal failure. Sobrado Marinho JS, Tomás Carmona I, Loureiro A, Limeres Posse J, García Caballero L, Diz Dios P. Med Oral Patol Oral Cir Bucal. 2007 Aug 1;12(4):E305- 10
- Dental abutment with a force transducer interfacing with a nerve (EN) PCT Patent WO/ 2010/ 106401 Marinho, Jorge.

Existing infrastructure

GW holds a private dental clinic and has access to premises of the Portuguese Oncology Institute at Porto, both equipped with all the means and equipment required to conduct the pre-clinical trials foreseen in work package 5.

4.1.6. Triteq, http:/ / www.triteq.com/

Triteq is a product design and development consultant company with inhouse manufacturing capabilities. Since 1992 our strategy has been to build a team of skilled people with an in-depth knowledge of technology and the ability to achieve innovative solutions to design challenges, from concept to prototype and every stage in-between.
The key expertise of the company is in working with products with a high regulatory burden, in particular medical devices. The team is able to help establish and prove a concept, and then work through the development to bring the device to market in an efficient fashion".
From idea conception all the way through to preparing products for the manufacturing process, we have every stage covered and the advantage of having all of these skills in house, ensures we remain connected with your project at every stage.
Our growth has been continuous and sustainable, always with a strong focus on bringing exceptional people to the business that thrive on challenges and appreciate the power of collaboration. Successful medical product design is vital an effective and efficient route to market.

We are a unique company, we research, design, engineer and manufacture. Our company has grown organically, so each highly skilled team has been built on solid foundations of knowledge, skills and experience

Role in the project:
Triteq will be involved mainly in the tasks pertaining to study of the mechanical and structural aspects of the SmarTooth implant as well as in those concerning assembling and packaging the two modules. Trite is the leader of work package 4.

Triteq: Profile of staff members

- **Ken Hall (Male)**

Ken Hall is Managing Director Triteq Innovations, Ken is a chartered engineer with over thirty years of experience in design and development of electronic products. He worked his way through the engineering ranks to Design Director in the data communications industry and designing distributed control system when he worked as technical director for Radamec Control Systems. Ken offers valuable advice to start ups and spin outs and is a regular guest speaker at universities, including Oxford and

Cambridge. His knowledge of medical product design and development is frequently sought by leading industry experts. Ken has a High level of commercial expertise in partnership development and design driven innovation to enable cost effective market entry for start- up's and spin-outs. Working with key stakeholders to identify and develop new areas of business and helping turn proof of principle developments into actual products.

Existing infrastructure
Triteq can manage and provide full manufacturing services for different types of products, covering all aspects of the assembly process to bring a final product together, packaged and ready to ship to the customer. Bespoke services include kitting, PCB development and wiring, enclosures, testing and bespoke packaging design and production, equipment and in-house facilities required to test functionality at extreme temperatures or in specific conditions.

4.1.7. Saliwell, http:/ / saliwell.com/ , (SW)

The company has created a platform for the generation of a variety of intra-oral intelligent diagnostic and therapeutic medical appliances, non-invasive to minimally invasive, with communication to extracorporeal devices. As an example, Saliwell has developed a solution to dry mouth (xerostomia) which restores natural saliva production through electro-stimulation. Saliwell has been active over 12 years in the development of intelligent intra-oral devices, mainly for (1) electrostimulation of nerves that control salivary secretion, aimed at increasing it to treat chronic dry mouth; and (2) delivery of medications to treat chronic diseases, such as Parkinson's disease. The electrostimulation device received CE & TGA approvals. Saliwell holds ISO certification for medical devices (ISO13485). We succeeded to sort out the adequate materials and sealing methods to keep the internal mechanism of the devices immune from external negative influence by the hostile oral milieu, and to handle the limited space available in the oral cavity and the significant mechanical forces exerted by the teeth and the tongue. In addition, we have high expertise in regulatory aspects for ISO 13484, CE, FDA, TGA etc. certification and in managing multi-national clinical trials, which will contribute to the performance of the foreseen clinical experiments and of exploitation activities.

Role in the project:
Saliwell will be responsible for the realization of the pre-clinical trials to evaluate the functionality of the developed SmarTooth prototype and including the evaluation of somatosensory response.

SW: Profile of staff members

- **Andy Wolff (Male)**
Dr. Andy Wolff (1952) is a dentist and Specialist in Oral Medicine. He graduated from Tel-Aviv University, Israel. He was born in Argentina and resides in Israel.
Dr. Wolff has been Visiting Fellow at the National Institutes of Health (USA), Director of the Saliva Clinic (Tel Aviv University), and Director of the Hospital Dentistry Department (Assuta Hospital, Israel). He served as the Director of 3 public dental clinics. Currently, he is the President of Saliwell Ltd., a company that is focused in intraoral medical devices. He is also the referent dentist for dental treatment under General Anesthesia for adults in the Tel-Aviv Sourasky Medical Center.
Dr. Wolff has authored over 70 publications in scientific journals and chapters in books, and holds 7 patents on medical devices. He is currently the Head of the Section "Medication-induced salivary gland dysfunction", 6th World Workshop on Oral Medicine.
Dr. Wolff has managed a number of animal and multinational human trials aimed at testing drugs and medical devices, and has been awarded 7 research grants from the European Commission (FP5, FP6 and FP7) to develop medical devices.
Dr. Wolff serves as reviewer and member of the editorial board of several scientific journals, and is member of a number of professional societies.

- **Eng. Ben Z. Beiski (Male)**
Holds a BSc. title in Electronic Engineering since 1981 and a MSc. degree in Bio-medical Engineering since 1987, both from Tel-Aviv University. He has 34 years of experience in managing technological companies and interdisciplinary projects, including projects dealing with intra-oral active appliances. In his former positions he was the chief engineer in the design of simulation system and high resolution graphic modeling for vehicles simulators (Simtech Ltd.) and has managed medical devices projects, such as

Anaesthesia Simulator for physicians, jointly with Leiden Univ. (NL) and Dräger AB (D). He coordinated two FP projects FP5- Saliwell and FP6-IntelliDrug. He has profound knowledge in technical aspects of medical devices, such as software, regulatory, QA, communications and electronics.

Both, A. Wolff and BZ Beiski, are diplomates in the management of clinical trials.

Publications:

1. A. Wolff, D. Herscovici, M. Rosenberg. A Simple Technique for Determination of Salivary Gland Hypofunction. Oral Surgery Oral Medicine Oral Pathology Oral Radiology and Endodontology, Vol. 94, 2002 (pp 175-178)
2. Smidt, A. Wolff. Implant-Supported Electro-Stimulating Device to Treat Xerostomia: A Preliminary Study. Clinical Implant Dentistry and Related Research, Vol. 12(1), 2010 (pp. 62-71)
3. F.P. Strietzel, G.I. Lafaurie, G.R. Bautista Mendoza, I. Alajbeg, S. Pejda, L. Vuletić, R. Mantilla, D.P. Falcão, S.C. Leal, A.C. Barreto Bezerra, S.D. Tran, H.A. Ménard, S. Kimoto, S. Pan, R.A. Martín-Granizo, M.L. Maniegas Lozano, S.L. Zunt, C.A. Krushinski, D. Melilli, G. Campisi, C. Paderni, S. Dolce, J.F. Yepes, L. Lindh, M. Koray, G. Mumcu, S. Elad, I. Zeevi, B.C. Aldape Barrios, R.M. López Sánchez, B.Z. Beiski, A. Wolff, Y.T. Konttinen. Efficacy and Safety of an Intraoral Electrostimulation Device for Xerostomia Relief: A Multicenter Randomized Trial. Arthritis & Rheumatism, Vol. 63, 2011 (pp. 180-190)
4. Alajbeg, D.P. Falcão, S.D. Tran, R.A. Martín-Granizo, G.I. Lafaurie, G.R. Bautista Mendoza, S. Pejda, L. Vuletić, R. Mantilla, S.C. Leal, A.C. Barreto Bezerra, H.A. Ménard, S. Kimoto, S. Pan, M.L. Maniegas Lozano, C.A. Krushinski, D. Melilli, G. Campisi, C. Paderni, D. Matranga, J.F. Yepes, L. Lindh, M. Koray, G. Mumcu, S. Elad, I. Zeevi, B.C. Aldape Barrios, R.M. López Sánchez, C. Lassauzay, O. Fromentin B.Z. Beiski, F.P. Strietzel, Y.T. Konttine, A. Wolff, S.L. Zunt. Intraoral Electrostimulator for Xerostomia Relief: A Long-term, Multicenter, Open-label, Uncontrolled, Clinical Trial. Oral Surgery Oral Medicine Oral Pathology Oral Radiology, Vol. 113, 2012 (pp. 773-781)
5. Paderni, G. Campisi, A. Schumacher, T. Göttsche, L. Giannola, V. De Caro, A. Wolff. Controlled Delivery of Naltrexone by an Intraoral Device: In Vivo Study on Human Beings. International Journal of Pharmaceutics, Vol. 452, 2013 (pp. 128-134)

Relevant previous projects or activities

1. 2002-04 A. Wolff and B.Z. Beiski, Assuta Hospital. Intelligent micro-sensor, electro-actuated, stimulator of salivary glands ("Saliwell"), European Commission, FP5-IST-2001-37409
2. 2004-07 B.Z. Beiski and A. Wolff, Assuta Hospital. Intelligent intraoral medicine delivery micro-system to treat addiction and chronic diseases ("IntelliDrug"), European Commission, FP6/ 2002/ IST/ 1-002243
3. 2004-07 B.Z. Beiski and A. Wolff, Assuta Hospital. Implantable micro-sensors and micro-systems for ambulatory measurement and control in medical products ("Healthy Aims"). European Commission, FP6/ 2002/ IST/ 1-001837
4. 2006-2008 B.Z. Beiski and A. Wolff, Saliwell Ltd. Plasma polymerization and barrier layers for integrated foil batteries and implantable micro batteries ("BattPlas"). German Federal Ministry of Education and Research (BMBF)
5. 2009-11 B. Z. Beiski and A. Wolff, Saliwell Ltd. Intra-oral device and intelligent system for diagnosis and monitoring of GERD (gastro-esophageal reflux disease) ("OralGERD"). EUREKA, pan-European network for market-oriented, industrial R&D

Existing infrastructure

SW holds a private clinic equipped with all the means and equipment required to conduct the pre-clinical trials foreseen in work package 5.

4.2. Third parties involved in the project (third party resources)

Please complete, for each participant, the following table (or simply state "No third parties involved", if applicable):

Universidade do Porto (UPorto)	
Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y

a) Production of mechanical parts according to UPorto design *b) Fabrication of Printed Circuit Boards* *c) Deposition of a piezoelectric layer on the piezoelectric sensors* *d) Catering for the project meetings* These tasks will be sub-contracted in case the specificities of the mechanical and electronic parts to be fabricated or of the equipment required to fabricate them are not available in the UPorto laboratories.

Does the participant envisage that part of its work is performed by linked third parties	N
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
If yes, please describe the third party and their contributions	

Technische Universiteit Delft (TUDelft)	
Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y
Mounting and Packaging service for electronics	
Does the participant envisage that part of its work is performed by linked third parties	N
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
If yes, please describe the third party and their contributions	

Fondazione Bruno Kessler (FBK)	
Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	N
If yes, please describe and justify the tasks to be subcontracted	
Does the participant envisage that part of its work is performed by linked third parties	Y

The Institute of Biophysics (IBF) was established in 2001 from the merging of five research centers of the National Research Council of Italy (CNR). The Institute is based in Genoa and has four separate research divisions located in Milan, Palermo, Pisa and Trento.
The IBF Unit at Trento (IBF-CNR@TN) is grouped around a main research focus dealing with biological membranes, macromolecular complexes and biomolecular imaging. In particular, the following research topics are faced and carried out in several biological models, from single molecules to living cells and organisms:
(1) Biophysics of pore-forming proteins. They are mainly bacterial toxins relevant for human health which form the weapons for attack or defense. They are excellent archetypal models for understanding key aspects of protein-protein and protein-lipid interactions; they are also employed in biotech

applications in many nanopore based tools.
(2) Molecular imaging is a new integrative discipline that enables non-invasive investigation of cellular functions and molecular processes in vivo under physiological or pathological conditions. We are developing new biosensors for monitoring selectively specific cellular functions and pathways.
(3) Photosensory biophysics of microbial, visual and non-visual opsins and biophysics of neurosystems.The aims are: i) to identify and characterize new types of channelrhodopsins for optogenetic applications, ii) to study electrophysiologically neural interfaces; and iii) to record ion activity in cells expressing neurodegenerative disorders.
(4) The superstructural organization of polysomes is investigated by using different nano-resolution imaging approaches to reveal the structural and functional details of translation.

As the main activities of the IBF-CNR@TN are focused on the understanding the mechanism of action of macro biomolecules with high relevance for human health and environmental impact, all the four labs constituting the Unit are formal and institutional part of the LaBSSAH thanks to an official agreement signed by FBK and CNR (23/ 07/ 2012).

The research core of IBF-CNR@TN has dealt historically with the study of the biophysical properties of natural and artificial biomembranes. Accordingly the third party will provide expertise and equipments for the electrophysiological study of the interaction between the chosen biosystems (model cells, neurons, nerves, nerve endings) with the artificial surfaces or, better, the non-biological components of the hybrid systems under exam.
To face this challenging aspects of the project, IBF-CNR@TN has already available: 1 setup for advanced patch-clamp analysis on living cells including piezoelectric micromanipulation systems; 3 setups for voltage-clamp of planar lipid membranes; and 1 semiautomatic patch-clamp system for living cells.

Staff effort: 27 person-months

Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	Y

Some FBK staff members that might be involved in the project, although regularly working for FBK, under FBK's control and at FBK premises, are employed by the Autonomous Province of Trento and have been seconded to FBK, as provided by the Provincial Law (Legge Provinciale) n. 14 of 2 August 2005, art.28.4, and by an ad-hoc Agreement.

The Autonomous Province of Trento (Provincia Autonoma di Trento – PAT - http:// www.provincia.tn.it/) is the local government body. It is the founding public body of Fondazione Bruno Kessler, which was established by Provincial Law 2 August 2005, No 14.

The Autonomous Province of Trento does not implement any action tasks in the project.

The costs related to the above-mentioned seconded personnel are refunded on a monthly basis by FBK to the Provincia Autonoma di Trento. These costs must be considered as in-kind contributions provided by a third party against payment, in compliance with Article 11 of the Grant Agreement.

Fraunhofer IZM (FGH)

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	N
If yes, please describe and justify the tasks to be subcontracted	
Does the participant envisage that part of its work is performed by linked third parties	N
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party	

Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
If yes, please describe the third party and their contributions	

GadgetWhisper (GW)	
Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	N
If yes, please describe and justify the tasks to be subcontracted	
Does the participant envisage that part of its work is performed by linked third parties	N
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
If yes, please describe the third party and their contributions	

Triteq (FGH)	
Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	N
If yes, please describe and justify the tasks to be subcontracted	
Does the participant envisage that part of its work is performed by linked third parties	N
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party	
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
If yes, please describe the third party and their contributions	

Saliwell (SW)	
Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	N
If yes, please describe and justify the tasks to be subcontracted	
Does the participant envisage that part of its work is performed by linked third parties	N
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party	

Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
If yes, please describe the third party and their contributions	

1 A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

4.3 External Advisory Board

Function

Assess and supervise ethics and gender equality issues. Assess the current design and documentation to identify the level of compliance against the AIMD Directive. Ensure that a sound framework allowing for potential future clinical trial or regulatory approval is in place. Discuss the design, creation and marketing strategy of SmarTooth as a future new product in the market. Determine the risks associated with technical issues as well as potential simplifications or enhancements which can be made. Investigate potential patent opportunities in the project results and prepare application procedures (in coordination with the EAB on Regulatory readiness).

Members

Prof. Ana Sofia Carvalho

Prof. Ana Sofia Carvalho (born 1973, Portugal) is Associate Professor with Aggregation in Bioethics from Catholic University of Portugal. She is the Coordinator of Office of Ethical Evaluation and Science Integrity in Portuguese Foundation for Science and Technology and Member of the National Council on Ethics in the Life Sciences - Elected by the Council of Rectors of Portuguese Universities (Parliament).
Since 2005 she is Director of the Institute of Bioethics at the Catholic University of Portugal. Professor Carvalho has been involved in a variety of interdisciplinary research projects that explore ethical and policy issues associated with a range of topics, including: research ethics and science integrity, ethical decision making process in oncology and intensive care, stem cell research, resource allocation in health care. This research has allowed her to publish over 55 articles and book chapters. She is also since FP6 an expert in the field of ethical evaluation of the European Commission (Marie Curie Grants, European Research Council, European Commission DG Research & Innovation: Directorate F - Health, Directorate B - B.6: Ethics and gender)

Dr. Marwan Abboud

Marwan Abboud has an electrical engineering degree from the Ecole Polytechnique of Beirut and a M. Sc. in Biomedical Engineering from the University of Montreal, Ecole Polytechnique. He is a member of the Order of Engineers of Quebec and Senior member of IEEE. Marwan is an inventor on more than 100 US patents and patent applications.
Marwan has over 25 years of successful senior engineering management experience. In 1995, Marwan Abboud co-created CryoCath Technologies Inc. He held critical leadership R&D position that enabled the company to become the leader in cryoablation after developing the first cryoablation catheter ever used on human in 1998. CryoCath was sold to Medtronic for 400 Million USD.
Marwan served for two years a critical position of Vice President of Advanced Research and Intellectual Property of AF Solutions at Medtronic and has held a number of leadership positions in the development medical devices.
Marwan's key strengths include strategic business development and extensive hands on experience with engineering functions and development and commercialization of medical devices. He has an extensive understanding of worldwide standards for safety of medical equipment as well as a great deal of experience in managing worldwide intellectual property portfolio and worldwide IP enforcement.

Prof. Gary K. Fedder

Vice Provost for Research, Howard M. Wilkoff Professor of Electrical and Computer Engineering, Carnegie Mellon University. He currently is the Howard M. Wilkoff Professor in ECE, professor in Robotics and has courtesy appointments in Mechanical Engineering and Biomedical Engineering.

In 1994, he obtained the Ph.D. degree in EECS from the University of California at Berkeley, where his research resulted in the first demonstration of multimode control of an underdamped surface-micromachined inertial device. His research interests include design and modeling of microsensors and microactuators, fabrication of integrated MEMS with electronic circuits using conventional CMOS processing, and implantable microsystems.

Currently, he serves as the Americas' regional editor for the IoP Journal of Micromechanics and Microengineering, on the editorial board of IET Micro & Nano Letters, and as co-editor of the Wiley-VCH Advanced Micro- and Nanosystems book series. He served on the editorial board of the IEEE Journal of Microelectromechanical Systems from 2001 to 2013 and on the editorial board of SPIE

Journal of Micro/ Nanolithography, MEMS, and MOEMS from 2010 to 2013. He served as the 2015 Transducers Conference regional program chair for the Americas, as general chair of the 2010 IEEE Sensors Conference, and as general co-chair of the 2005 IEEE MEMS Conference. Professor Fedder has contributed to over 250 research publications and holds 13 patents in the MEMS area.
The diverse set of research projects in his group links to a long-term trend toward low-cost intelligent systems that benefit from embedded MEMS, often merged with other emerging technologies, for example, nanomaterials, 3D printing and soft robotics. Active projects include MEMS system modeling and design methodologies, accelerometers and gyroscopes for motion sensing, ultra-compliant neural probes, piezoelectric energy scavenging for implantable pressure sensors, nonlinear parametric microresonators, and self-healing RF microresonator oscillators and filters. Challenges include system design, process integration, and physical modeling including environmental effects.

Section 5: Ethics and Security

5.1 Ethics

SmarTooth aims at restoring dental sensitivity resorting to an implant that transforms occlusion mechanical forces into electrical impulses to be delivered to the trigeminal nerve endings. SmarTooth transforms dental implants into active prosthesis, restoring dental sensitivity. It is meant for people who already have dental implants, to prevent dental overload, mastication motor function impairment, and improving body balance and posture.
Therefore, the main ethical issues that are involved in the methodologies that will be applied include: research with adult healthy volunteers, data protection and privacy. It is only planned, at this phase, to involve participants who already have dental implants; therefore, if new dental implants will be implanted in heathy volunteers, in order to fulfil the number of participants necessary for the research to be statistically significant, all the details and approvals will be provided to EC before the commencement of relevant experiments. Israel will be involved and will comply with all ethical and legal requirements of H2020.

RESEARCH WITH HUMAN PARTICIPANTS
Only participants able to consent will be involved. The exclusion criteria includes: the standard exclusion criteria for EEG, participants with head and neck pathologies and participants with other medical devices implanted.
Informed consent will always be obtained before participants begin their participation. Participants will read an informed consent form and then indicate their agreement (or lack of agreement) to participate by signing an informed consent form. During this process a member of the team will be available to respond to any question or doubts of the research participant.
The participants will be recruited in private and public sector hospitals. All necessary ethical approvals will be obtained and forwarded to EC. EEG and ECG will be performed in these patients therefore only no invasive techniques will be used. The information and consent forms will be developed and will include:

(a) all the details concerning any potential risk or/ and burden of the research
(b) information on the personal sensitive data that will be collected, used and stored
(c) the voluntariness of the participation and the right to make any questions at any time
(d) the right to withdraw at any phase of the project;
(e) incidental finding policy (the participant and the responsible physician will be contacted if incidental results are obtained)
(f) contacts of the PI

These forms will be designed in a language that can be understandable to the participants involved and will be provided to EC before the respective research task.

DATA PROTECTION AND PRIVACY
Any information obtained during the course of the studies will be kept strictly confidential. All personal data will be stored in a manner in which participants cannot be identified with their personal data. All data will be pseudo-anonymised (coded) and only the PI will have access to this information. The data

will be stored in a password protected computer. Data files with participants' identifying information and their corresponding data will never be stored on the same computer.

Copies of the legal approvals for the collection of personal data by the National Data Protection Commission will be provided to EC before the collection of any data. The project will be in full compliance with the Directive 95/46/EC and the consortium ensures that any research activities that will take place after the new regulation has entered into force will comply with the provisions therein.

NON EU COUNTRY
A partner from Israel will be involved and all the ethical standards and guidelines of Horizon2020 will be rigorously applied and data will be imported to EU will have all the necessary authorisations.

5.2 Security[1]

Please indicate if your project will involve:

- activities or results raising security issues: (NO)
- 'EU-classified information' as background or results: (NO)

[1] Article 37.1 of the Model Grant Agreement: *Before disclosing results of activities raising security issues to a third party (including affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the Commission/Agency.* Article 37.2: *Activities related to 'classified deliverables' must comply with the 'security requirements' until they are declassified. Action tasks related to classified deliverables may not be subcontracted without prior explicit written approval from the Commission/Agency. The beneficiaries must inform the coordinator — which must immediately inform the Commission/Agency — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55).*

Department of Dental Medicine
Division head
Mats Trulsson Professor

During the last three years I have, together with my research team, been in contact with Dr Jorge Marinho and the implant sensitive concept developed by him. We find his ideas extremely interesting and if the plans can be realized it will definitely be a major breakthrough in oral rehabilitation.
We have in our research showed that the normal sensory motor regulation of biting and chewing is severely disturbed when sensory signals from the periodontal receptors around natural teeth are absent. When natural teeth are extracted and dental implants are installed the periodontal receptors disappears. This result in an impaired control of low manipulative forces used to hold and position food between the teeth (Trulsson and Gunne 1996), high biting forces used to split food (Svensson and Trulsson 2011) and strong forces used to crush food during chewing (Grigoriadis, Johansson and Trulsson 2011). If the implant sensitive concept by Dr Jorge Marinho can be realized we hope to be able to restore the lost dental sensitivity and rehabilitate the impaired motor functions in patients with dental implants.

Best regards,

Mats Trulsson DDS, PhD.
Professor in Oral Rehabilitation
Head of Division of Oral Rehabilitation
Department of Dental Medicine
Karolinska Institutet
Sweden

References:
Grigoriadis A, Johansson RS, Trulsson M: Adaptability of mastication in people with implant-supported bridges. J Clin Periodontol 38(4):395-404, 2011.

Svensson KG and Trulsson M: Force control during food holding and biting in subjects with tooth- or implant-supported fixed prosthesis. J Clin Periodontol, In Press, 2011.

Trulsson M and Gunne H S J: Food-holding and -biting behavior in human subjects lacking periodontal receptors. J Dent Res, 77(4): 574-582, 1998.

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