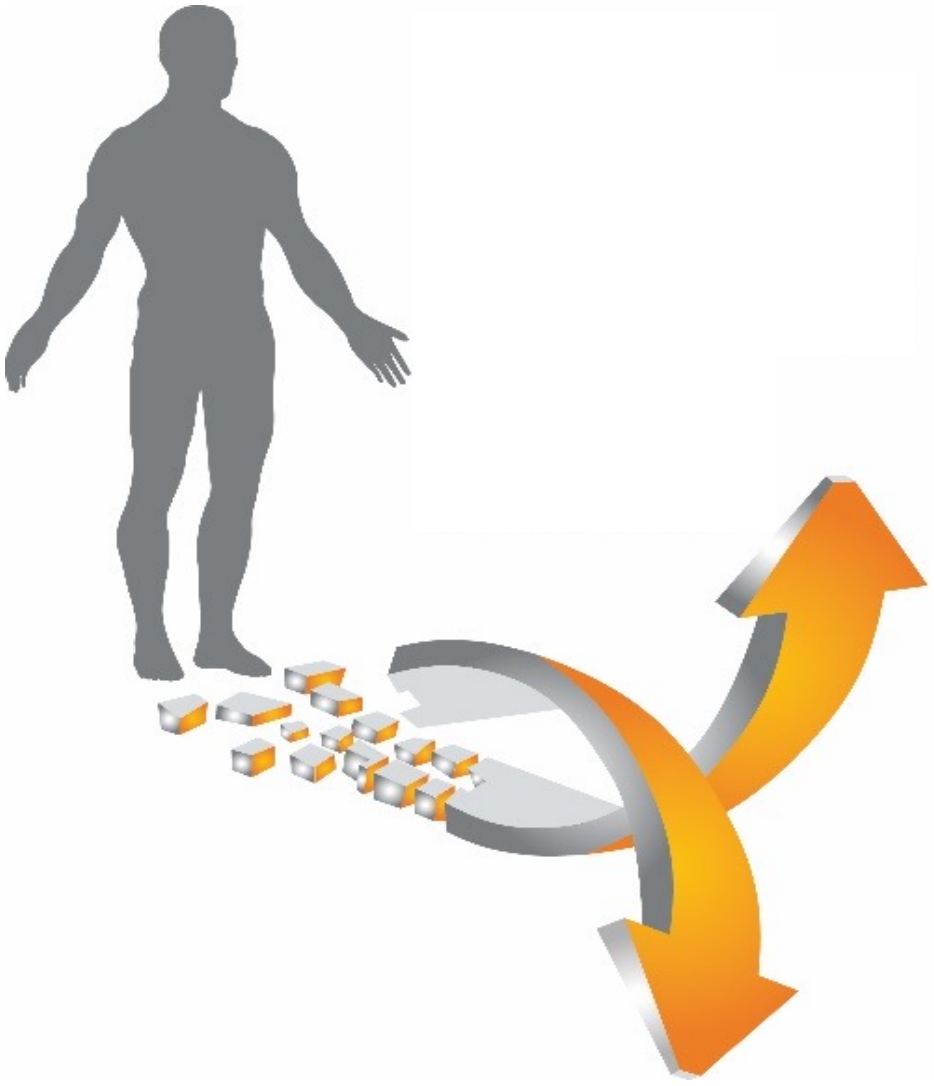
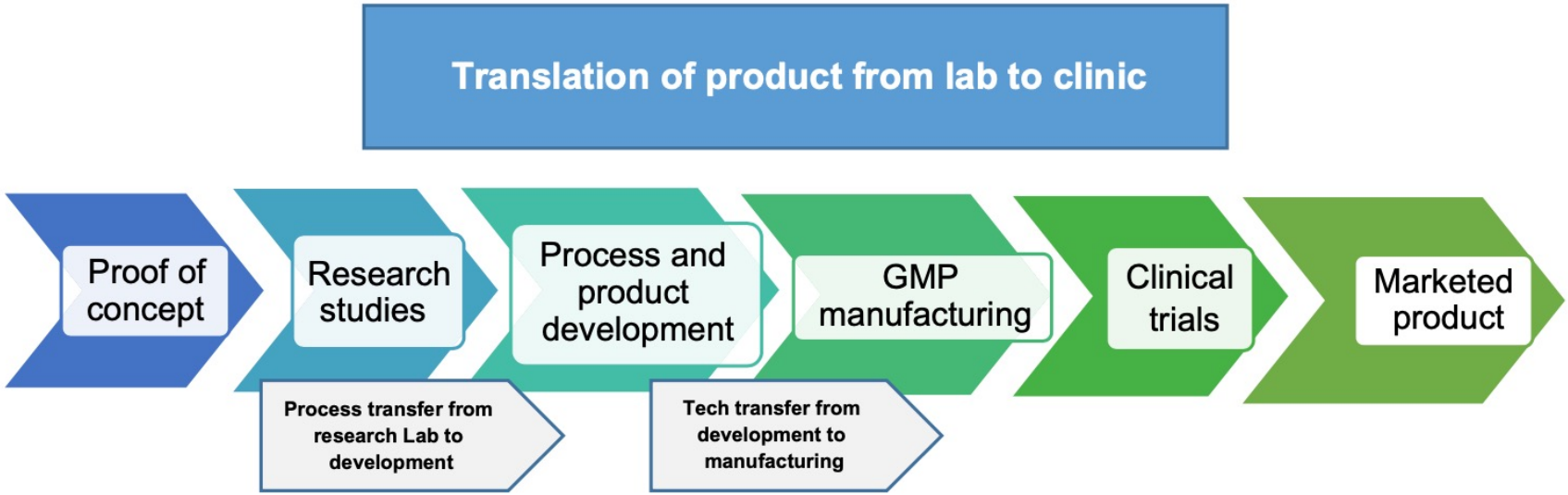
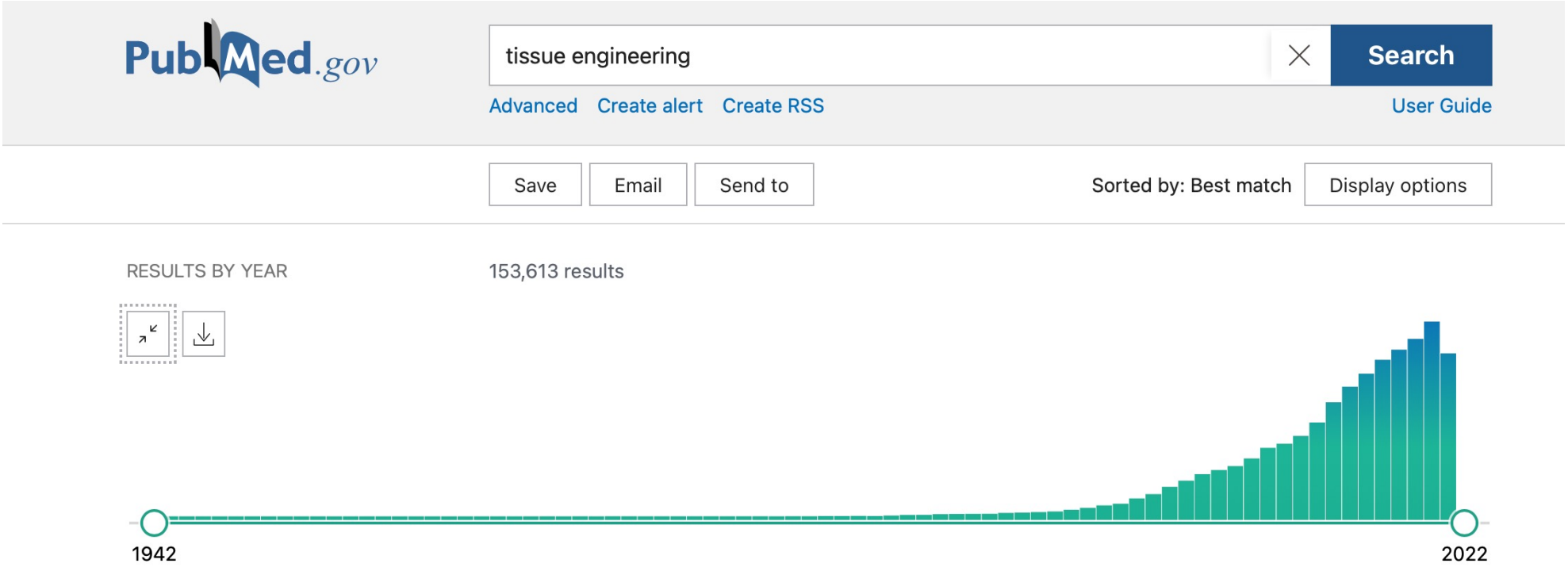


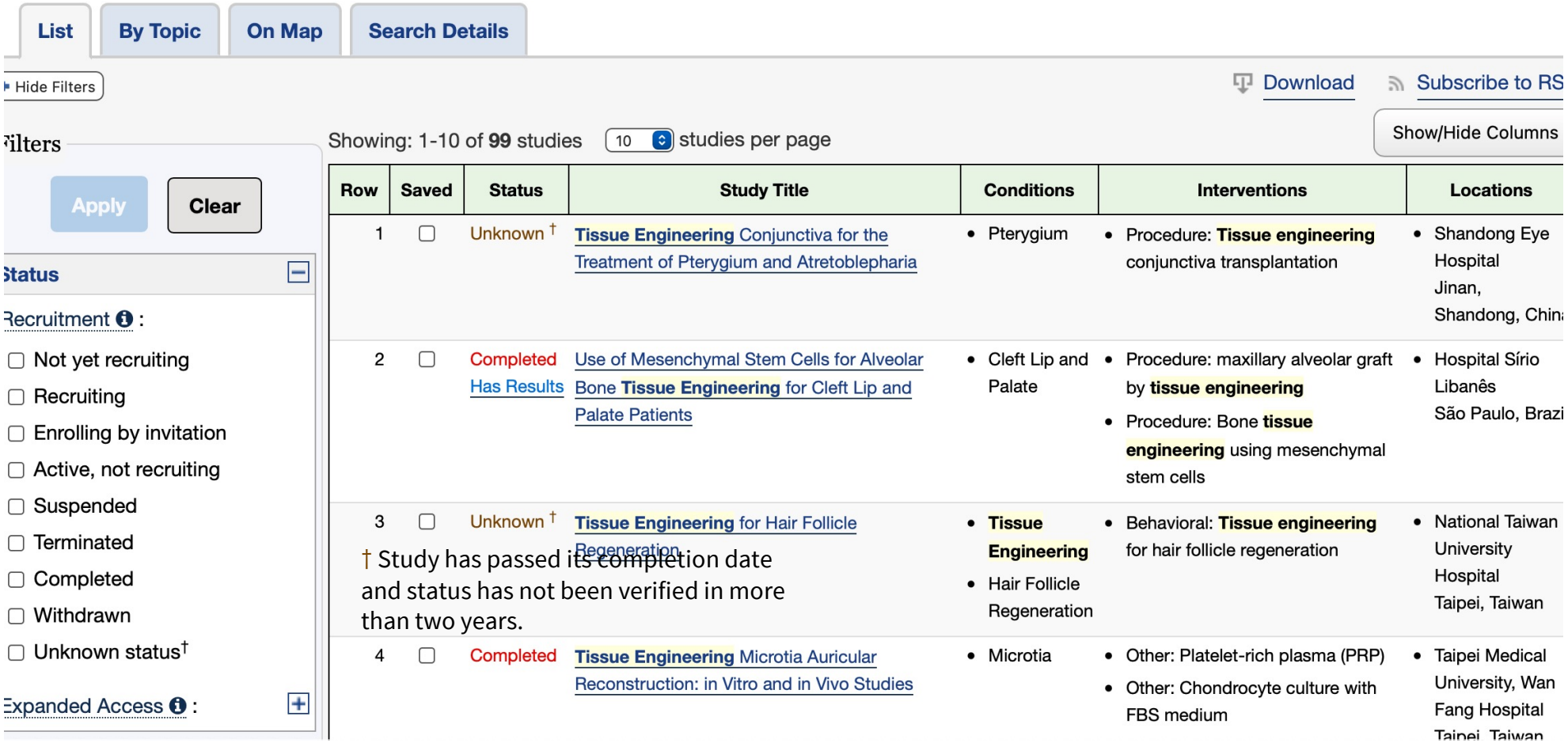
TE CLINICAL TRIALS


Translation of product from lab to clinic
Proof of concept
Research studies
Process and product development
GMP manufacturing
Clinical trials
Marketed product
Process transfer from research Lab to development
Tech transfer from development to manufacturing

Clinical trials in Tissue engineering



https://clinicaltrials.gov



ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

https://clinicaltrials.gov

List | By Topic | On Map | Search Details

Conditions related to search results

See All Studies by Topic

Conditions

- Alphabetical
- By Category

Rare Diseases

- Alphabetical

Drug Interventions

- Alphabetical
- By Category

Dietary Supplements

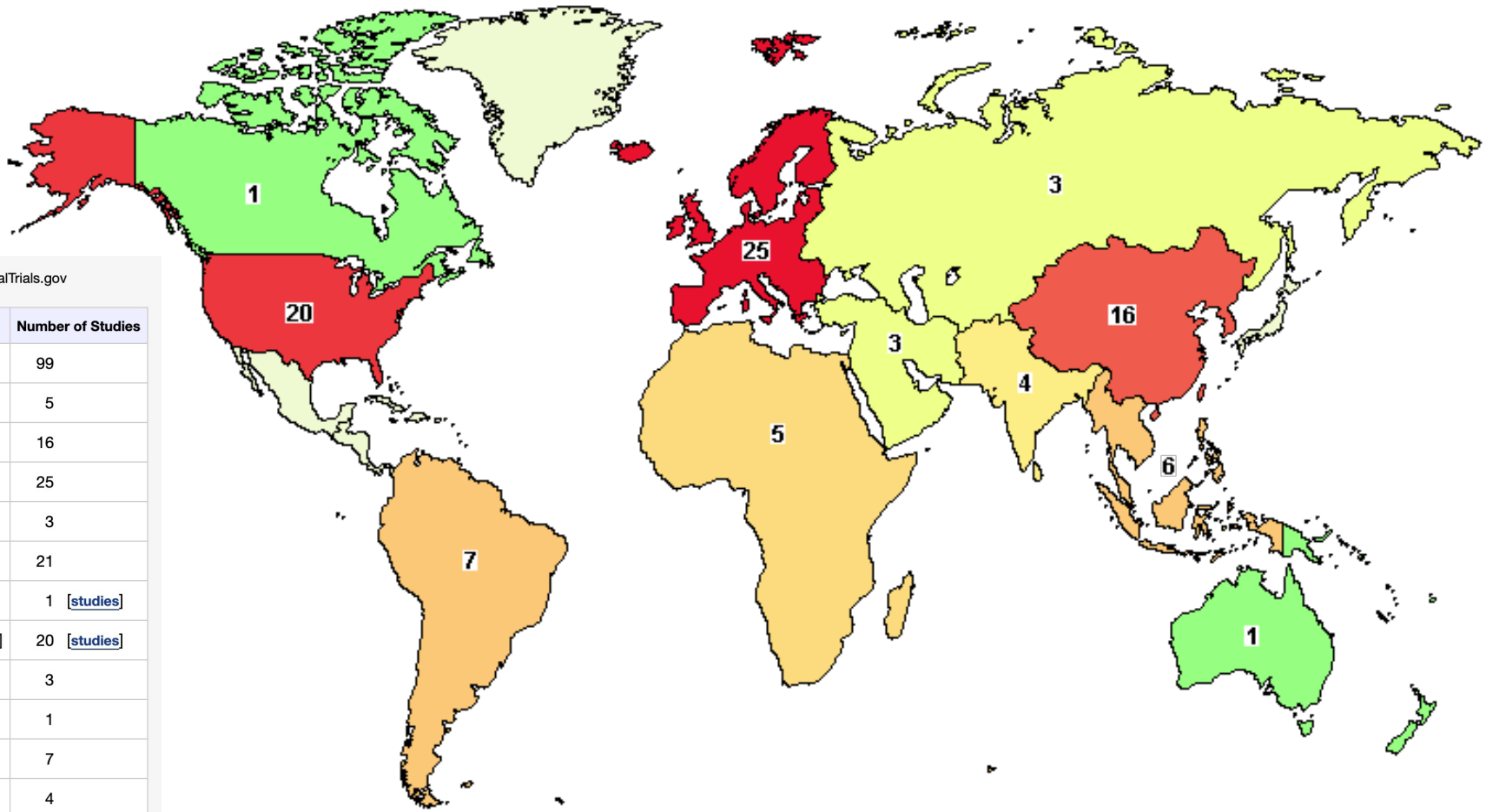
- Alphabetical

25 per page

Find in Table:

Conditions	Studies
Alveolar Bone Loss	2
Aortic Valve Disease	1
Aortic Valve Stenosis	1
Arrhythmias, Cardiac	1
Arteriovenous Fistula	1
Arthritis	2
Atrophy	5
Autoimmune Diseases	1
Autoimmune Diseases of the Nervous System	1
Back Pain	1
Becker Muscular Dystrophy	1

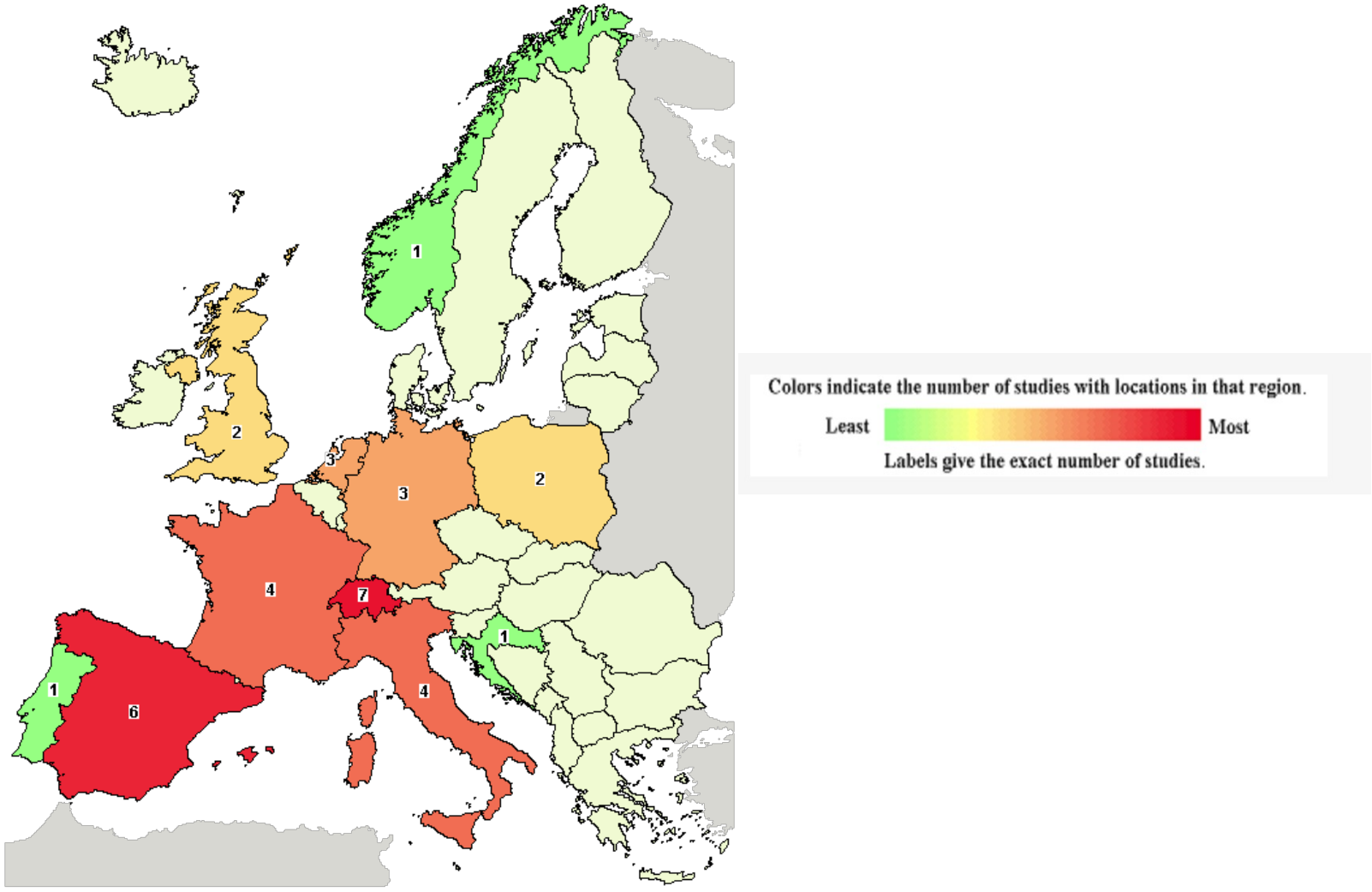
https://clinicaltrials.gov



Source:https://ClinicalTrials.gov

Region Name	Number of Studies
World	99
Africa [map]	5
East Asia [map]	16
Europe [map]	25
Middle East [map]	3
North America	21
Canada [map]	1 [studies]
United States [map]	20 [studies]
North Asia [map]	3
Pacifica [map]	1
South America [map]	7
South Asia [map]	4
Southeast Asia [map]	6

https://clinicaltrials.gov



Recruitment status

- **Not yet recruiting:** The study has not started recruiting participants.
- **Recruiting:** The study is currently recruiting participants.
- **Enrolling by invitation:** The study is selecting its participants from a population, or group of people, decided on by the researchers in advance. These studies are not open to everyone who meets the eligibility criteria but only to people in that particular population, who are specifically invited to participate.
- **Active, not recruiting:** The study is ongoing, and participants are receiving an intervention or being examined, but potential participants are not currently being recruited or enrolled.
- **Suspended:** The study has stopped early but may start again.
- **Terminated:** The study has stopped early and will not start again. Participants are no longer being examined or treated.
- **Completed:** The study has ended normally, and participants are no longer being examined or treated (that is, the last participant's last visit has occurred).
- **Withdrawn:** The study stopped early, before enrolling its first participant.
- **Unknown:** A study on ClinicalTrials.gov whose last known status was recruiting; not yet recruiting; or active, not recruiting but that has passed its completion date, and the status has not been last verified within the past 2 years.

Apply Clear

Status

Recruitment :

- [ ] Not yet recruiting
- [ ] Recruiting
- [ ] Enrolling by invitation
- [ ] Active, not recruiting
- [ ] Suspended
- [ ] Terminated
- [ ] Completed
- [ ] Withdrawn
- [ ] Unknown status†

Expanded Access :

Eligibility Criteria

Age :

years OR

Age Group:

- [ ] Child (birth–17)
- [ ] Adult (18–64)
- [ ] Older Adult (65+)

Sex :

- ( ) All
- ( ) Female
- ( ) Male

- [ ] Accepts Healthy Volunteers

Study Type

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	☐	Active, not recruiting	Clinical Trial for the Regeneration of Cartilage Lesions in the Knee	• Tear; Knee, Cartilage, Articular	• Other: **Tissue** Engineered Product	• University Hospital Sveti Duh Zagreb, Croatia • Universitätsklinikum Freiburg Freiburg, Germany • Orthopädische Klinik König-Ludwig-Haus Würzburg, Germany • (and 2 more...)
2	☐	Recruiting	Study With an Autologous Dermo-epidermal Skin Substitute for the Treatment of Full-Th	• Skin Wound	• Biological: EHSG-KF • Biological: STSG	• Chirurgia Plastica e Centro Ustioni Azienda Ospedaliera di Rilievo Nazionale A. Cardarelli Napoli, **Italy** • Unità di Chirurgia Plastica e Ustioni Ospedale Santobono Napoli, **Italy** • U.O.C. Grandi Ustionati Azienda Ospedale Università Padova Padova, **Italy** • (and 6 more...)
3	☐	Recruiting	Study With an Autologous Dermo-epidermal Skin Substitute for the Treatment of Burns in Children	• Burns	• Biological: EHSG-KF • Biological: STSG	• Unità di Chirurgia Plastica e Ustioni Ospedale Santobono Napoli, **Italy** • U.O.C. Grandi Ustionati Azienda Ospedale Università Padova Padova, **Italy** • Città della Salute Torino, **Italy** • (and 3 more...)
4	☐	Recruiting	Study With an Autologous Dermo-epidermal Skin Substitute for the Treatment of Burns in Adults	• Burns	• Biological: EHSG-KF • Biological: STSG	• Chirurgia Plastica e Centro Grandi Ustioni Azienda Ospedaliera di Rilievo Nazionale A. Cardarelli Napoli, **Italy** • Unità di Chirurgia Plastica e Ustioni Ospedale Santobono Napoli, **Italy** • U.O.C. Grandi Ustionati Azienda Ospedale Università Padova

Show study NCT03394612: Study With an Autologous Dermo-epidermal Skin Substitute for the Treatment of Full-Thickness Skin Defects in Adults and Children

•Active, not recruiting: The study is ongoing, and participants are receiving an intervention or being examined, but potential participants are not currently being recruited or enrolled.

Recruiting: The study is currently recruiting participants.

Italy

Istituto Ortopedico Galeazzi (IOG)
Milan, **Italy**, 20161

How to Read a Study Record

Study Details
The Study Details is the default view. It provides complete information about a study, including the following:

STUDY DESCRIPTION
This section explains what the researchers will do during the clinical study and why they are conducting the study, and it specifies what condition or disease is being studied and the questions that the researchers want to answer.

STUDY DESIGN
This section explains the investigative methods or strategies used in the clinical study. It also provides other Information, such as study type, estimated or actual enrollment, study start and completion dates, and official study title.

ARMS AND INTERVENTIONS (FOR INTERVENTIONAL STUDIES) OR GROUPS AND COHORTS (FOR OBSERVATIONAL STUDIES)
For interventional studies (clinical trials), this section explains the type of intervention/treatment participants receive, what the dosage is for drugs, and how long the participants receive the intervention.
For observational studies, this section explains the participant groups that are observed and any treatments or exposures that are of interest in the study.

OUTCOME MEASURES
This section describes the measurements planned in the study protocol that are used to determine the effects of intervention or treatment on participants. Types of outcome measures include primary outcome measures, secondary outcome measures, and other pre-specified measures.
For observational studies, this section explains the participant groups that are observed and any treatments or exposures that are of interest in the study.

ELIGIBILITY CRITERIA
This section explains who can participate in the study. The most common criteria are listed first: ages eligible for the study, sexes eligible for study, and whether the study accepts healthy volunteers. A list of additional inclusion and exclusion criteria is also provided in this section.

CONTACTS AND LOCATIONS
This section contains the study's ClinicalTrials.gov Identifier (NCT Number) and contact information for the study investigators when the study is recruiting participants. The study location is shown below the study sponsor's contact information. If the study is being conducted in many locations, click on the **Show Study Locations** link to see a complete list of locations. The recruitment status appears next to each location.

Clinical Trial for the Regeneration of Cartilage Lesions in the Knee (NosetoKnee2)

ClinicalTrials.gov Identifier: NCT02673905

Recruitment Status : Active, not recruiting
First Posted : February 4, 2016
Last Update Posted : January 6, 2021

Sponsor:
University Hospital, Basel, Switzerland

Collaborators:
University Hospital Freiburg
Istituto Ortopedico Galeazzi
General Hospital Sveti Duh
Fraunhofer-Institut für Silicatforschung ISC
Orthopaedische Klinik Koenig-Ludwig-Haus

Information provided by (Responsible Party):
University Hospital, Basel, Switzerland

STUDY DESCRIPTION

This section explains what the researchers will do during the clinical study and why they are conducting the study, and it specifies what condition or disease is being studied and the questions that the researchers want to answer.

Study Description

Go to

Brief Summary:
The purpose of this study is to investigate the efficacy of an engineered cartilage transplant (N-TEC) in comparison to a cell-activated matrix (N-CAM) for the treatment of articular cartilage lesions in the knee. The main innovations in this trial are the use of nasal chondrocytes and the implantation of a **tissue** in contrast to cells seeded on a matrix. The goals of the trial are to: (i) evaluate whether implantation of a more mature graft (**tissue** therapy) is beneficial for the quality and durability of the repair **tissue** and the clinical outcome, (ii)determine the potential of the mature graft to integrate with the adjacent cartilage and form hyaline repair **tissue** and (iii) assess the efficacy of each treatment in correlation to the characteristics of the defect (e.g. "acute" versus "chronic" setting).

Condition or disease	Intervention/treatment	Phase
Tear; Knee, Cartilage, Articular	Other: **Tissue** Engineered Product	Not Applicable

STUDY DESIGN

This section explains the investigative methods or strategies used in the clinical study. It also provides other Information, such as study type, estimated or actual enrollment, study start and completion dates, and official study title.

Study Design Go to

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	108 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Randomized, Multi-center Phase II Clinical Trial for the Regeneration of Cartilage Lesions in the Knee Using Nasal Chondrocyte-based **Tissue** (N-TEC) or Nasal Chondrocyte-based Cell (N-CAM)-Therapies
Study Start Date :	November 2016
Estimated Primary Completion Date :	December 2022
Estimated Study Completion Date :	December 2022

ARMS AND INTERVENTIONS (FOR INTERVENTIONAL STUDIES) OR GROUPS AND COHORTS (FOR OBSERVATIONAL STUDIES)

For interventional studies (clinical trials), this section explains the type of intervention/treatment participants receive, what the dosage is for drugs, and how long the participants receive the intervention.

For observational studies, this section explains the participant groups that are observed and any treatments or exposures that are of interest in the study.

Arm	Intervention/treatment
Experimental: N-TEC (**tissue** engineered product) N-TEC is based on autologous nasal chondrocytes expanded and further cultured on type I/III collagen membrane for 2 weeks to allow the cells to produce extracellular matrix containing cartilage specific Proteins. The IMP is implanted in the knee joint and secured by sutures.	Other: **Tissue** Engineered Product Implantation of **tissue** engineered products Other Names: • N-TEC (**tissue**) • N-CAM (Cell activated matrix)
Experimental: N-CAM (**tissue** engineered product) N-Cell activated Matrix (CAM) is based on autologous nasal chondrocytes expanded and further cultured on type I/III collagen membrane for 2 days only to allow the cells to adhere. The IMP is implanted in the knee joint and secured by sutures.	Other: **Tissue** Engineered Product Implantation of **tissue** engineered products Other Names: • N-TEC (**tissue**) • N-CAM (Cell activated matrix)

OUTCOME MEASURES

This section describes the measurements planned in the study protocol that are used to determine the effects of intervention or treatment on participants. Types of outcome measures include primary outcome measures, secondary outcome measures, and other pre-specified measures.

Outcome Measures Go to

Primary Outcome Measures :

1. comparison of the efficacy of the two investigational medicinal products (IMPs) [Time Frame: 24 months]

   Assessment whether a **tissue** therapy will improve the clinical efficacy for the patient, leading to an increase of at least 10 points in the main primary outcome (self-assessed score KOOS) after 24 months as compared to the cell therapy group

In a clinical study's protocol, the planned outcome measure that is the most important for evaluating the effect of an intervention/treatment. Most clinical studies have one primary outcome measure, but some have more than one.

Secondary Outcome Measures :

1. stability and Integration of the implanted IMP [Time Frame: 24 months]

   Assessment of the stability and Integration of the graft with the adjacent **tissues** by magnetic resonance observation of cartilage repair **tissue** (MOCART Score) derived from the MRI as well as the remodeling of the implanted grafts towards native cartilage assessed by delayed gadolinium-enhanced MRI of cartilage (dGEMRIC) evaluation from the 24-month follow-up

2. efficacy for patient [Time Frame: 24 months]

   Improvement of the KOOS-Score from baseline to 24 months

In a clinical study's protocol, a planned outcome measure that is not as important as the primary outcome measure for evaluating the effect of an intervention but is still of interest. Most clinical studies have more than one secondary outcome measure.

Other Outcome Measures:

1. efficacy of IMPs related to acute vs. chronic lesions [Time Frame: 24 months]

   Determination if one treatment is more beneficial than the other in a certain setting (onset of symptoms) (retrospective Analysis)

2. safety of IMPs [Time Frame: 24 months]

ELIGIBILITY CRITERIA

This section explains who can participate in the study. The most common criteria are listed first: ages eligible for the study, sexes eligible for study, and whether the study accepts healthy volunteers. A list of additional inclusion and exclusion criteria is also provided in this section.

Eligibility Criteria Go to

Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years to 65 Years (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patient is ≥18 and ≤65 years old at time of screening.
  - Patient has a localized articular cartilage defect of the femoral condyle and/or the trochlea of the knee. 2 localized cartilage defects are accepted if the total defect size is ≤ 8 cm2, both cartilage defects are located at the femoral condyle and/or the trochlea and both cartilage defects are to be treated with N-CAM or N-TEC.
  - Patient has a defect of grade 3 or 4 according to the ICRS classification.
  - Patient has a defect size ≥2 and ≤8 cm2 as assessed by MRI/arthroscopy.
  - Patient has an intact (≤ICRS Grade 2) articulating joint surface (no "kissing lesions").
  - Patient has an intact meniscus (maximum 1/2-resection).
  - Patient has a stable knee joint or sufficiently reconstructed ligaments. If not, ligament repair has to be done during the operation or within 6 weeks of the planned cartilage treatment.
  - Patient has a maximum baseline score of 75/100 in the KOOS subjective knee evaluation.
  - Patient is willing and able to give written informed consent to participate in the study and to comply with all study requirements, including attending all follow-up visits and assessments and to complete postoperative rehabilitation regimen.

Exclusion Criteria:

- Patient is the investigator or any sub-investigator, research assistant, pharmacist, study coordinator, other staff or relative thereof directly involved in the conduct of the protocol or in a dependency or employment with the sponsor.
- Patient is unable to understand the patient information

Contacts and Locations

Go to

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02673905***

Locations

Croatia

University Hospital Sveti Duh
Zagreb, Croatia, 10000

Germany

Universitätsklinikum Freiburg
Freiburg, Germany, 79106

Orthopädische Klinik König-Ludwig-Haus
Würzburg, Germany, 97074

Italy

Istituto Ortopedico Galeazzi (IOG)
Milan, **Italy**, 20161

Switzerland

University Hospital Basel
Basel, Switzerland, 4031

Study Locations link to see a complete list of locations.
The recruitment status appears next to each location.