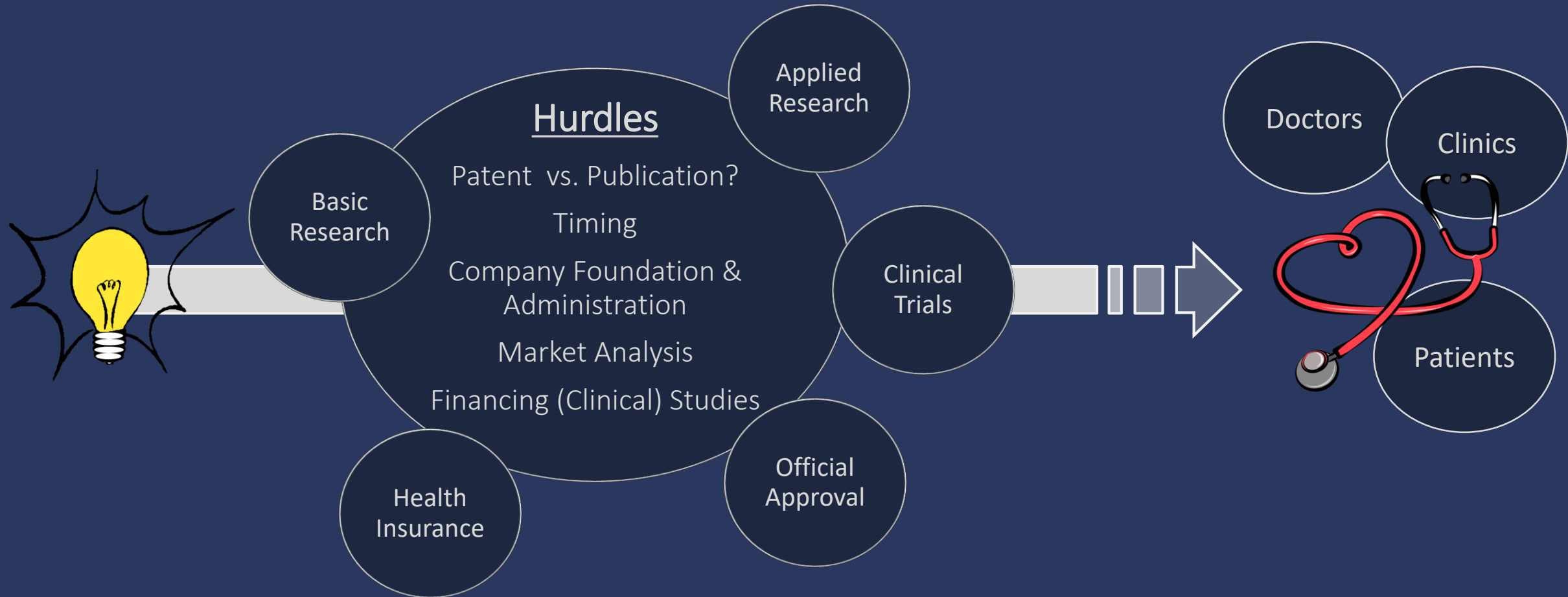


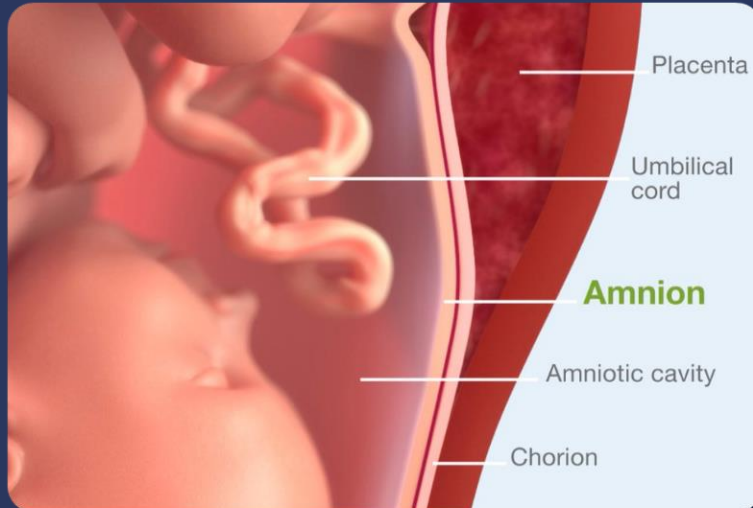
Transferring Research Knowledge to Clinical Practice Challenges and Chances

Prof. Dr. med. habil. Katrin Engelmann, Dr. Marcus Binner
May 21, 2019

Chemnitz Seminar “MEMS Technologies and Applications”



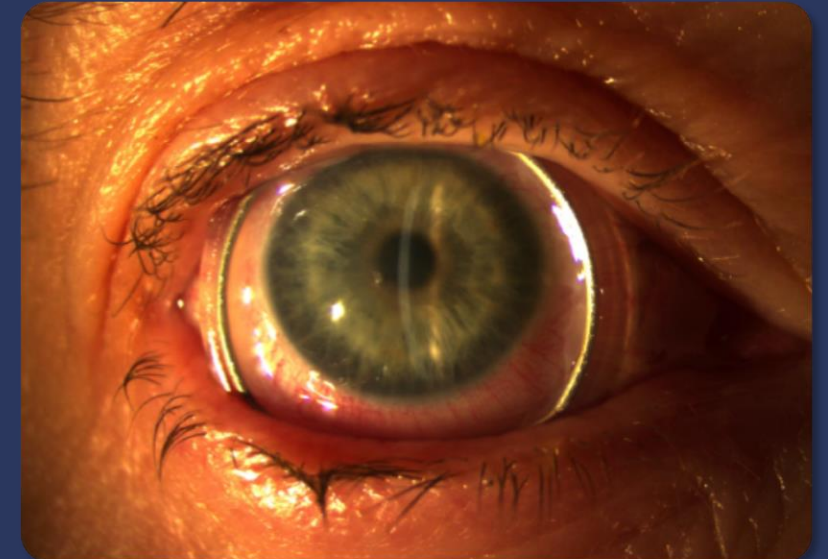
Project aim: suture-free amnion membrane transplantation



<https://pbs.twimg.com/media/DT5IHCdU0AA9gi2.jpg>



final assembly



application

Benefits: ambulant treatment, no operation, repeatable

Indication: corneal surface damage (scars, chemical burn, infectious keratitis...)
recently: dry eye – “Office Eye Syndrome” (GER: 12 Mio. patients)

“Bottlenecks”

Patents

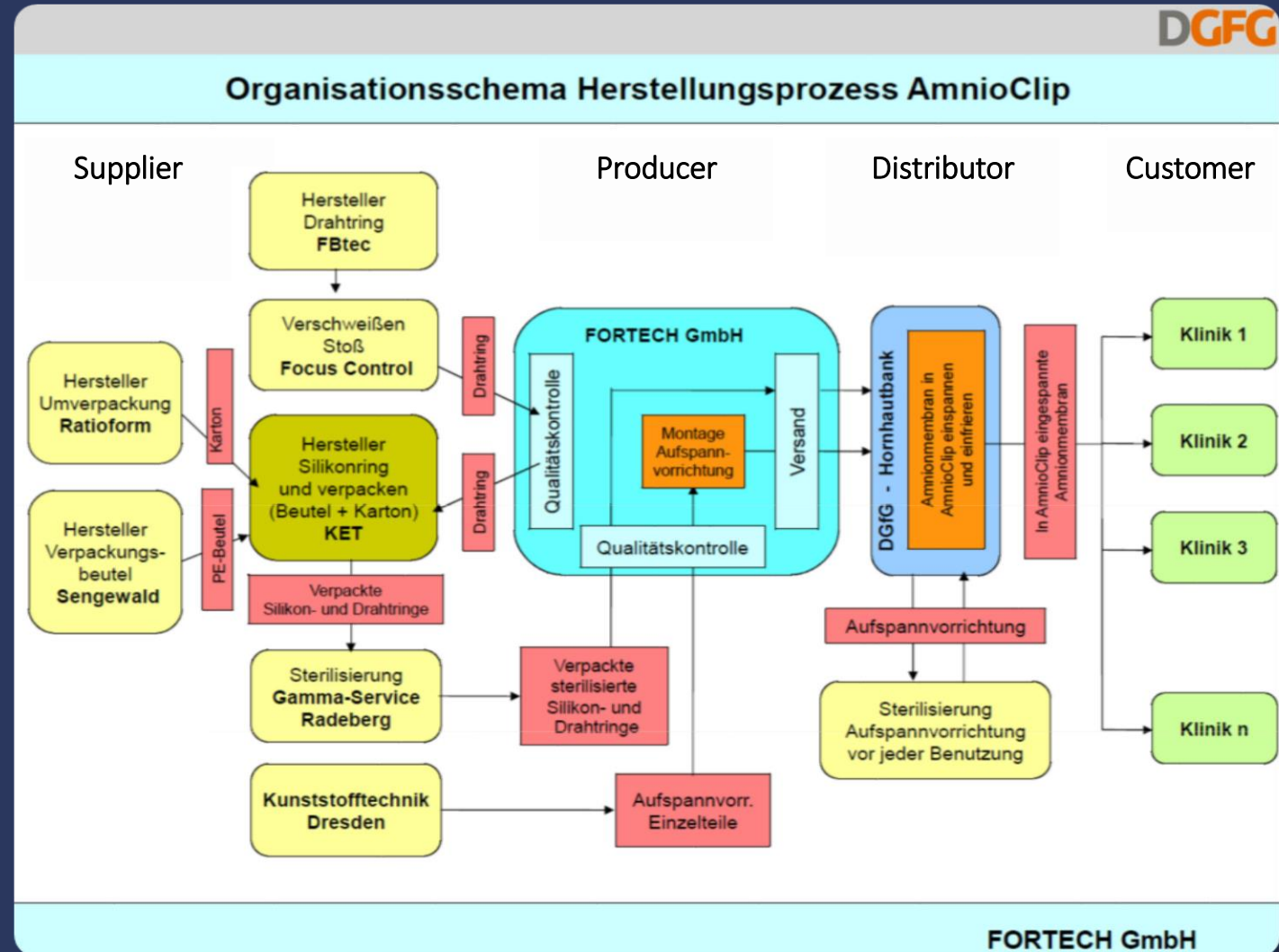
Usage Studies (Research)

Consistent Quality Management

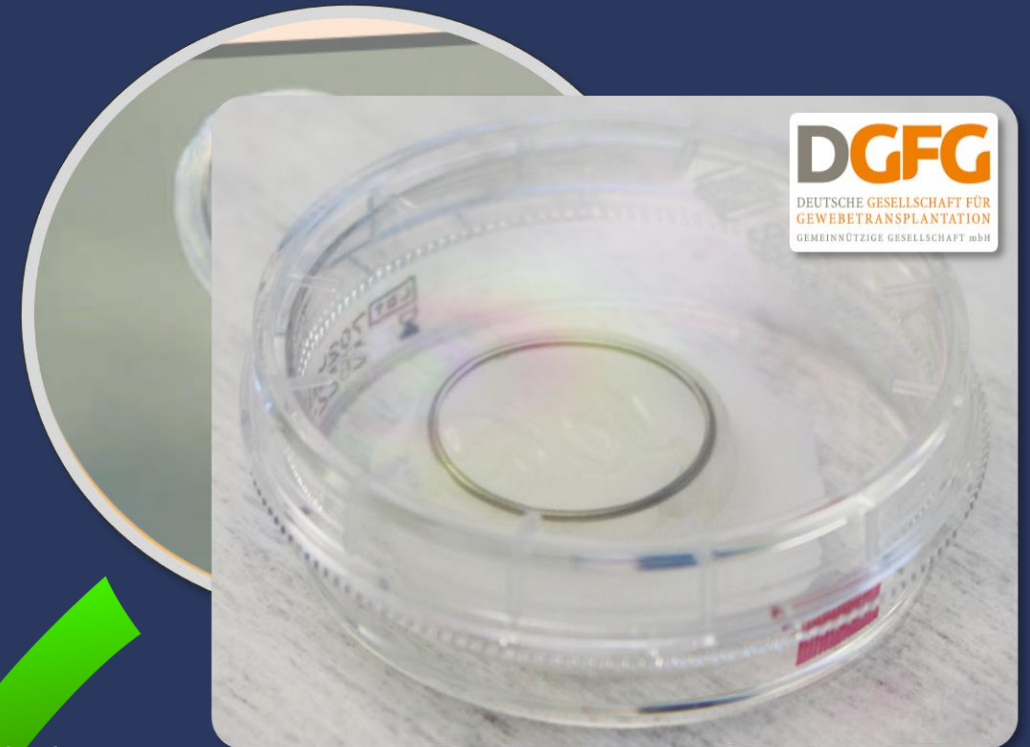
License by DGFG

Official Approval for German
Healthcare applications (PEI)

Time besides clinical routine

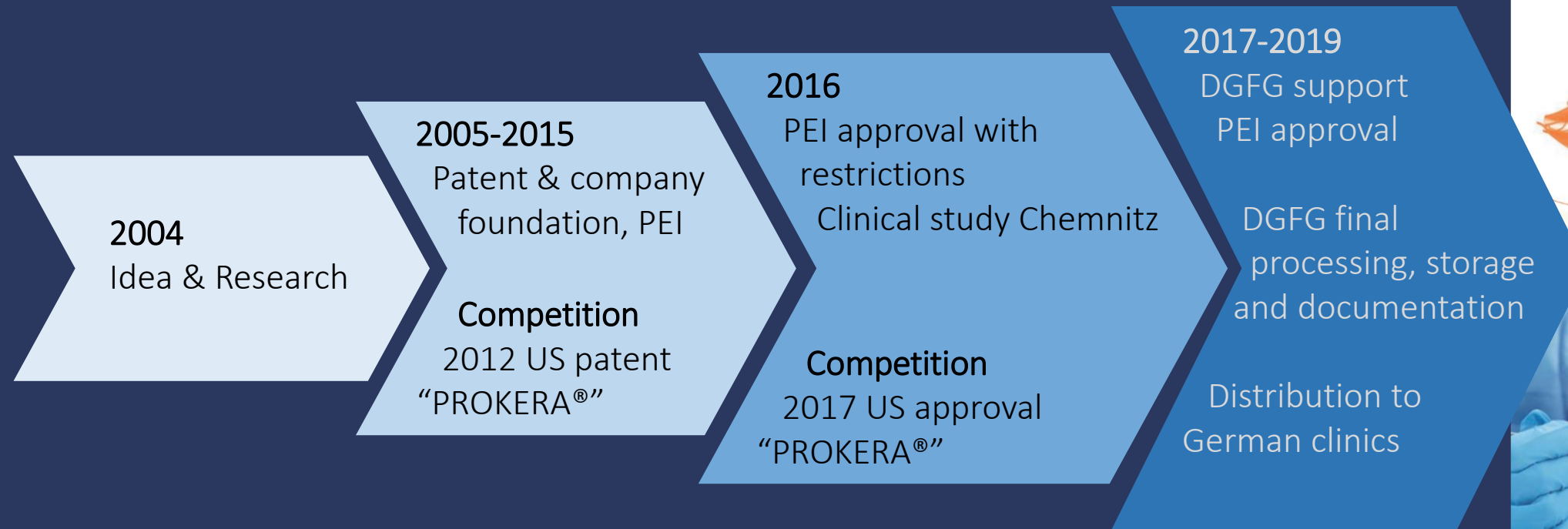


- Intense discussions with Paul-Ehrlich-Institute
 - Preliminary approval with restrictions: Effect of AM orientation should be studied in clinical surrounding (risk management for production)
 - Klinikum Chemnitz: study completed (2017)
 - Beneficial: in parallel AM approval for general wound healing applications
 - DGFG for assembly and distribution
-
- **Nowdays: Official approval for dry eye disease!**
 - **DGFG is allowed to distribute the AC+ to German clinics**



PEI.G.11968.01.1

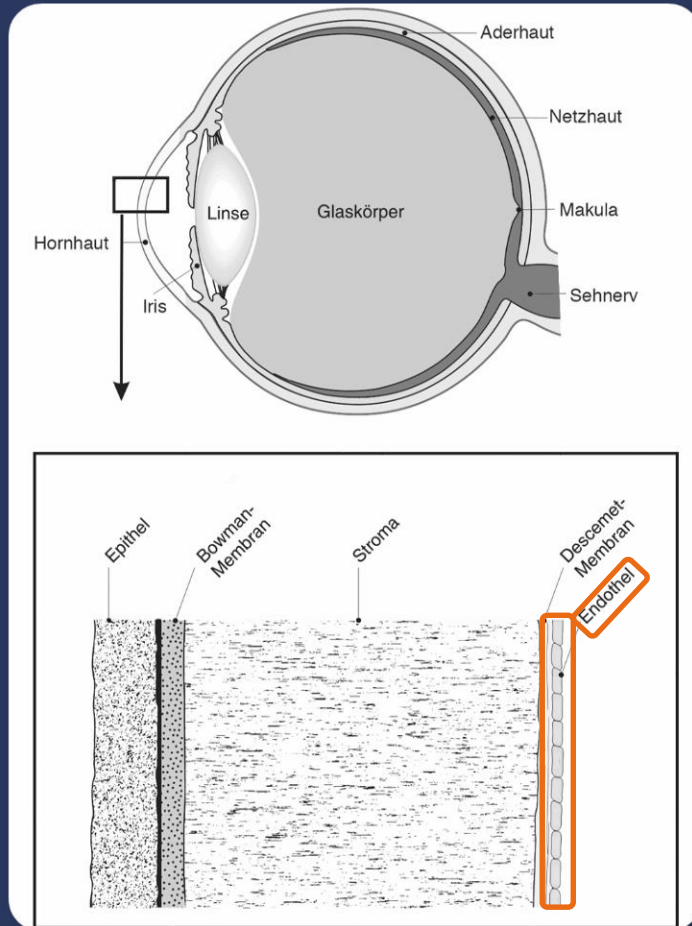
A long pathway until medical approval...



Leibniz-Institute of Polymer Research Dresden



- one of the largest polymer research facility in GER
 - application oriented fundamental research
 - synthesis, characterization, theory, processing & testing of novel materials
 - 2017: 480 employees & > 950 publications per year
-
- knowledge transfer project for medical applications
 - innovative solutions for hydrogel applications
 - materials for artificial cornea production, storage and transportation



Anatomie und Funktion der Hornhaut 2008, Universitäts-Augenklinik Tübingen

The Cornea is the
„Window of the Eye“.

Corneal Curvature affects the
Visual Acuity.

The Endothelium is responsible for the
Visual Transparency.

While the Corneal Epithelium has
regenerative potential,
The Endothelium is non-regenerative.

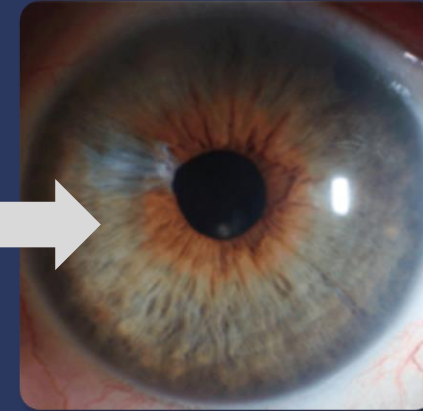
Turbid Vision
Damaged Endothelium



www.coavision.wordpress.com 2018

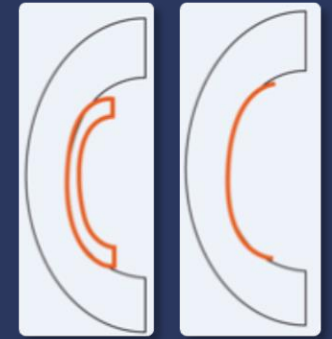


J. Am. Assoc. Pediatr. Ophthalmol. Strabismus. 2008, 12, 314–316.



Cornea after DSEK/DMEK

Ophthalmol. Zeitschrift der Dtsch. Ophthalmol. Gesellschaft 2011, 108, 825–832.



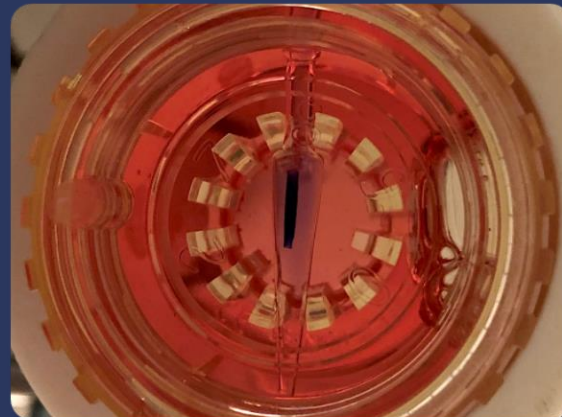
DSEK

DMEK

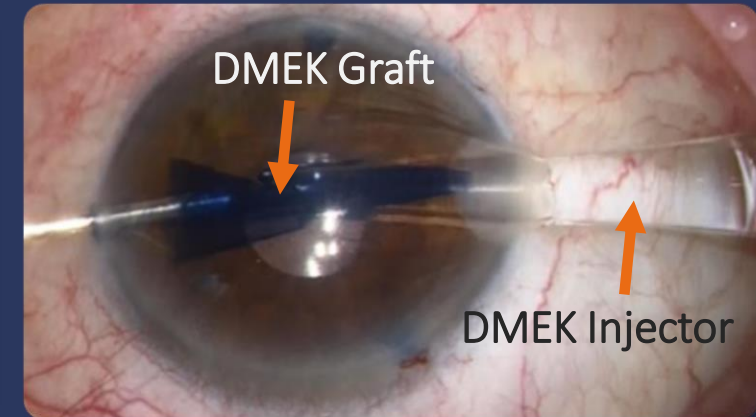
DMEK operation
Stripping
Loading
Injection



DGFG 2017



Miracles in Sight 2018



Augenklinik Saar – Sulzbach 2016



Today

12.7 Million people worldwide suffering from corneal blindness.

Int. J. Ophthalmol. 2017, 10. 1154–1162.



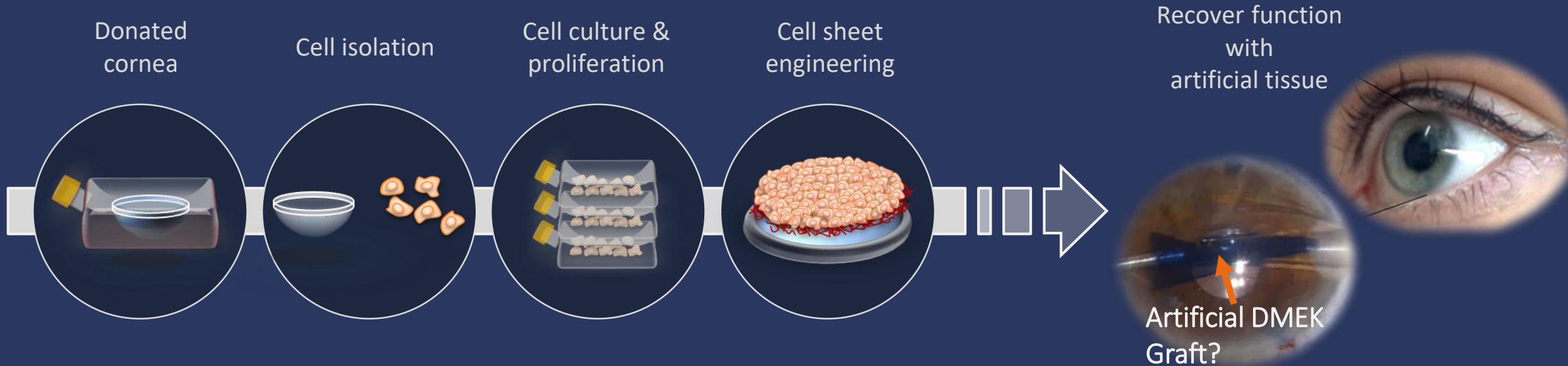
Only **1 out of 70 Patients** receives a corneal transplant.



Future

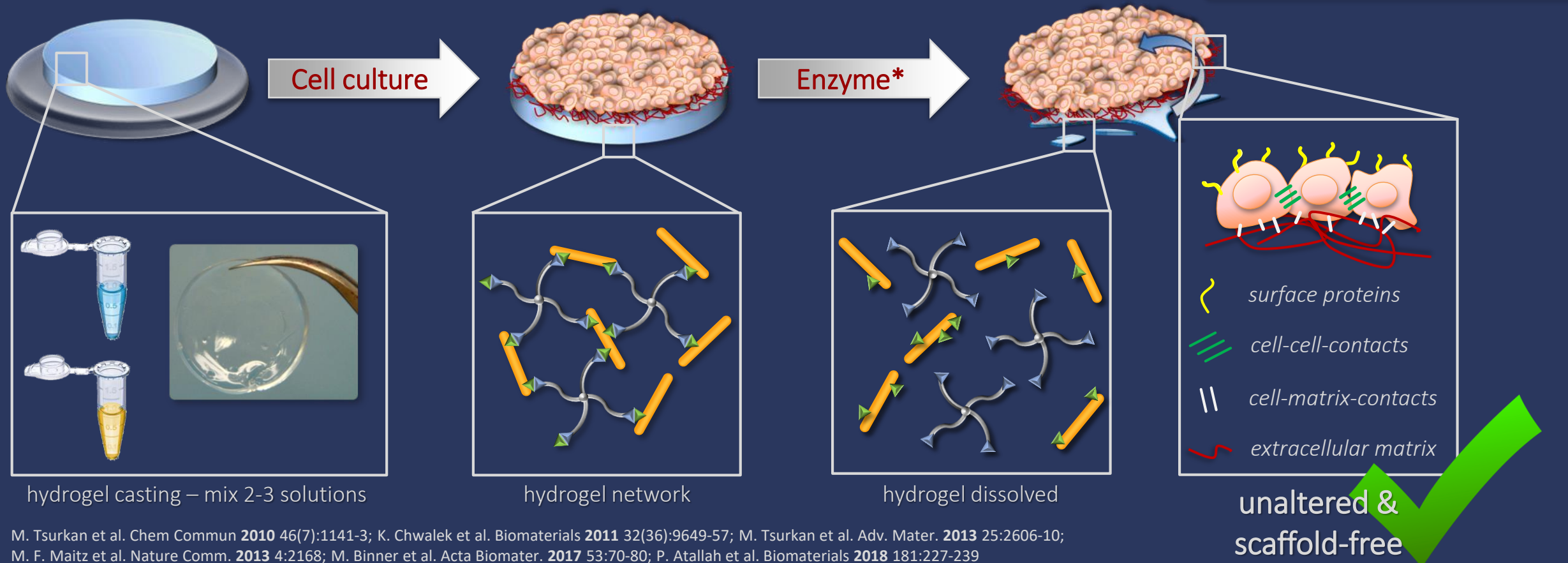
Artificially produced tissues will **cover the global demand.**

Ex vivo tissue production



How to collect and transfer
the engineered tissue?

Enzymatically cleavable hydrogels for tissue production



M. Tsurkan et al. Chem Commun **2010** 46(7):1141-3; K. Chwalek et al. Biomaterials **2011** 32(36):9649-57; M. Tsurkan et al. Adv. Mater. **2013** 25:2606-10; M. F. Maitz et al. Nature Comm. **2013** 4:2168; M. Binner et al. Acta Biomater. **2017** 53:70-80; P. Atallah et al. Biomaterials **2018** 181:227-239

Can it be translated to clinics?



Prof. Dr. Alfonso L. Sabater
Dr. Enrique Salero
Angela Gomez



Elizabeth Fout-Caraza, MHSA
William Brian Buras Sr., CEBT

“Bottlenecks”

- Patent transfer
- Labspace
- GMP production
- Certification
- Clinical Trials
- Approval of new therapies



cell culture products

Follow-up financing!

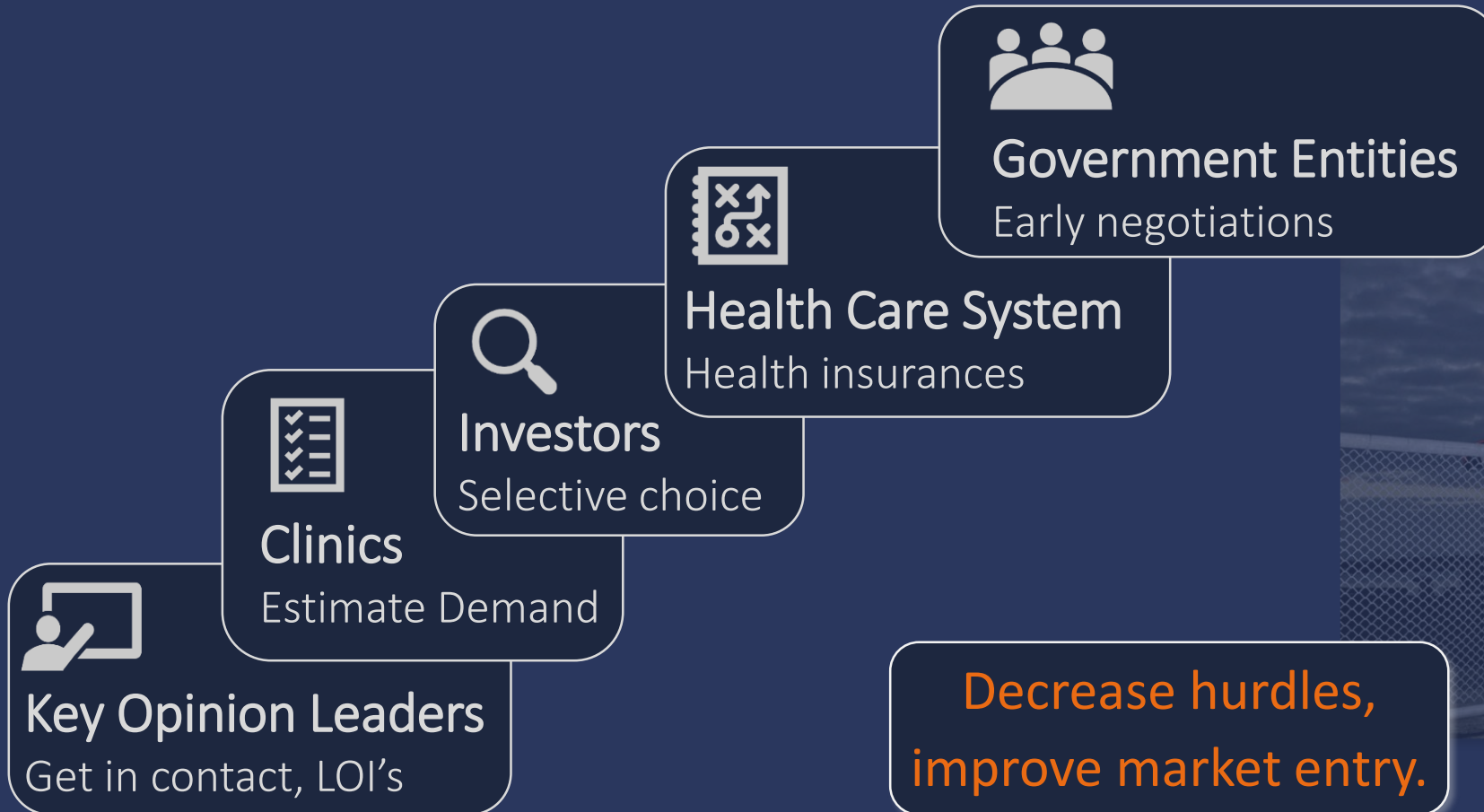


customized hydrogel precursors



coinwire.com 2019

Aim: Create methods/how-to's as template for bio-/medtech & pharma start-up's



**Decrease hurdles,
improve market entry.**

The clinical ecosystem program to conduct market entry process

Innovation Assistant

Communication with clinicians, searching for new projects

“Template” to guide from idea towards market entry

Manage contacts to KOL's, clinics, government entities, investors

Use Cases

Document and present examples of successful knowledge transfer projects

Valuable tool to arise interest, e.g. of investors

Direct feedback to Innovation Assistant

Digital Clinic

Develop new therapy algorithms with regards to government regulations

University degree program to implement “application-oriented thinking” to clinicians

Strengthen regional economy as innovation leader.

THANK YOU FOR YOUR ATTENTION.

Dr. Marcus Binner

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Please scan QR code for my contact details.

The project TissueGUARD is part of the EXIST program and is funded by the German Federal Ministry for Economic Affairs and Energy (BMWi) and the European Social Fund (ESF) as well as the Leibniz Institute of Polymer Research Dresden (IPF) Germany.