

Guido Moll, PhD, Engineer MedBT
BIH & CHARITÉ Berlin – Germany



**– Refined Clinical Translation in
Precision Medicine, Regenerative Medicine
and Novel Personalized Therapies –**

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Diploma Engineer – Med. Biotech, Regen. Medicine, Immunology
Technical University of Berlin, Berlin, Germany (2000-2007) &
QLD Inst Med Res (QIMR), Brisbane, Australia (2004-2005)

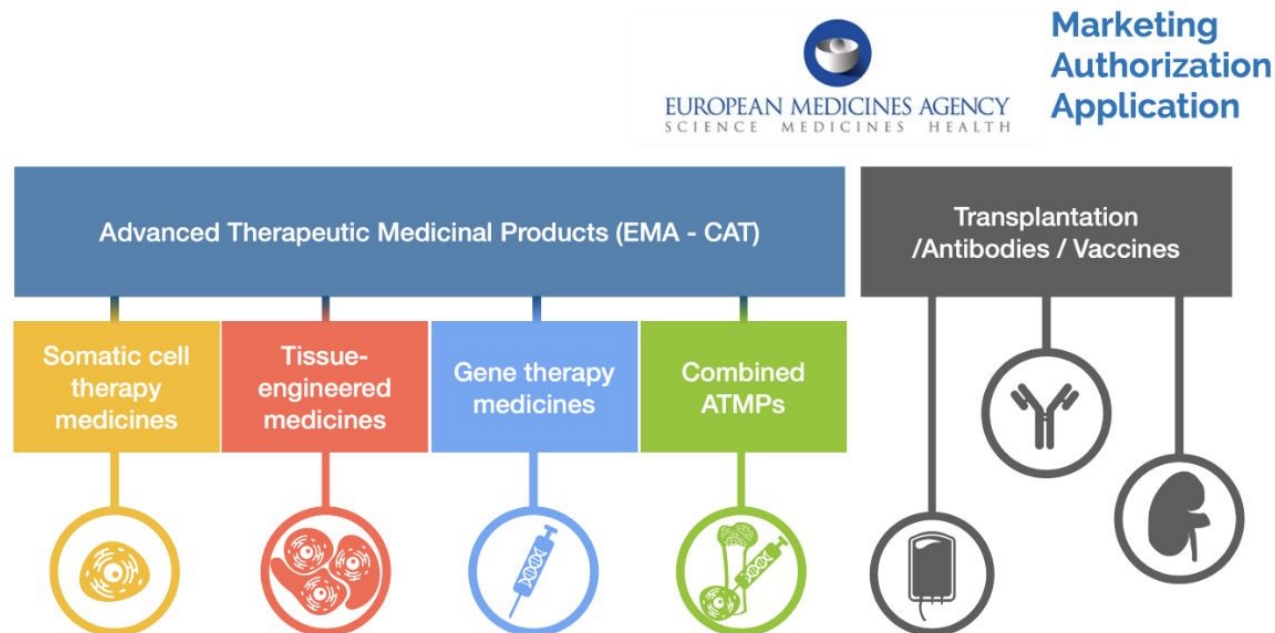
PhD – Clinical Immunology, Hematology, Regenerative Medicine
Karolinska Institutet and Uppsala University,
Stockholm and Uppsala, Sweden (2007-2014)

PostDoc / PI – Berlin Institute of Health (BIH – 2014-2025) &
Charité Universitätsmedizin Berlin, Germany (2014-2025)
BIH Center for Regenerative Therapies (BCRT)
Julius Wolff Institute (JWI) for Musculo-Skeletal Research
Dept of Nephrology and Internal Intensive Care Medicine

<https://www.researchgate.net/profile/Guido-Moll>



High Medical Need Advanced Therapies



Advanced Therapies:

**ATMPs (Europe)
CGTs (US)**

**Personalized
Therapies**

Precision Medicine

Indications: Oncology, Regenerative medicine (Cardiology, Neurology), Genetic diseases

Advanced Therapy Medicinal Products (ATMPs) / Cell and Gene Therapies (CGTs) typically require Good Manufacturing Practice (GMP) Manufacturing – Complex Regulatory Approval and Marketing Authorization

<https://www.cevidra.com/advanced-therapy-medicinal-products/>

High Medical Need Advanced Therapies

Advanced Therapies are Complementary to Established Medical Procedures....



Conventional Surgery

e.g. solid organ transplants (SOT)
kidney, liver, heart and lung...

Conventional Pharm. Drugs

e.g. hypertension, anticoagulation,
immunosuppression in SOT/HSCT

Radio and Chemotherapy

e.g. treatment of solid cancer and
haematological diseases in HSCT

Advanced Therapies...

ATMPs/CGTs, Precision Medicine,
Personalized Therapies

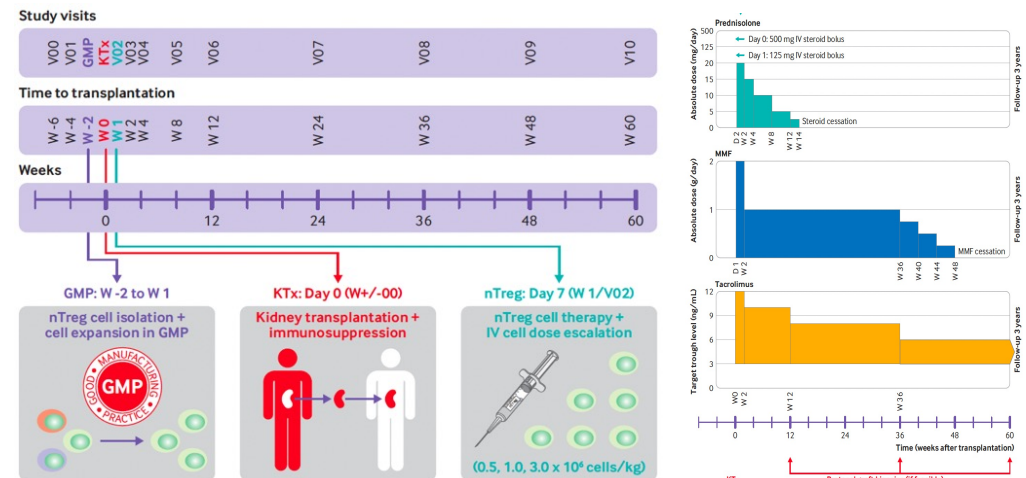
Römhild Otto Moll & Babel Volk Reinke et al. – The BMJ 2020

<https://www.bmj.com/content/371/bmj.m3734>

thebmj | BMJ 2020;371:m3734 | doi: 10.1136/bmj.m3734

Regulatory T cells for minimising immune suppression in kidney transplantation: phase I/IIa clinical trial

Andy Roemhild,^{1,2} Natalie Maureen Otto,^{1,2,3} Guido Moll,¹ Mohamed Abou-El-Enein,^{1,2} Daniel Kaiser,^{1,2} Gantuja Bold,^{1,3} Thomas Schachtner,^{1,3} Mira Choi,³ Robert Oellinger,⁴ Sybille Landwehr-Kenzel,^{1,2} Karsten Juerchott,^{1,5} Birgit Sawitzki,^{1,5} Cordula Giesler,^{1,2,3} Anett Sefrin,^{1,2,3} Carola Beier,^{1,2} Dimitrios Laurin Wagner,^{1,2} Stephan Schlickeiser,^{1,5} Mathias Streitz,^{1,5} Michael Schmueck-Henneresse,^{1,2} Leila Amini,^{1,2} Ulrik Stervbo,⁶ Nina Babel,^{1,5,6} Hans-Dieter Volk,^{1,2,5} Petra Reinke^{1,2,3}





FAPESP
WEEK
GERMANY

March 25-26th, 2025

High Medical Need Advanced Therapies

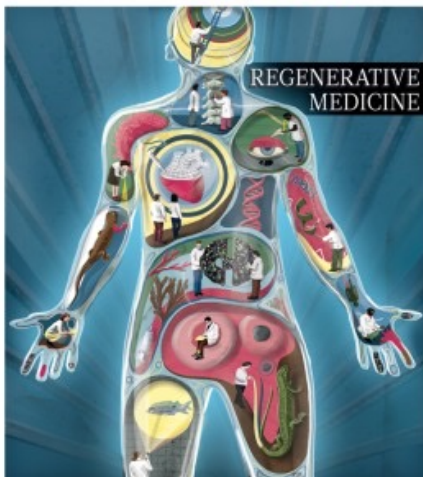


The Future Looks Bright – In Principle...



BIH Regeneration
BIH Center for Regenerative Therapies (BCRT)

natureOUTLOOK



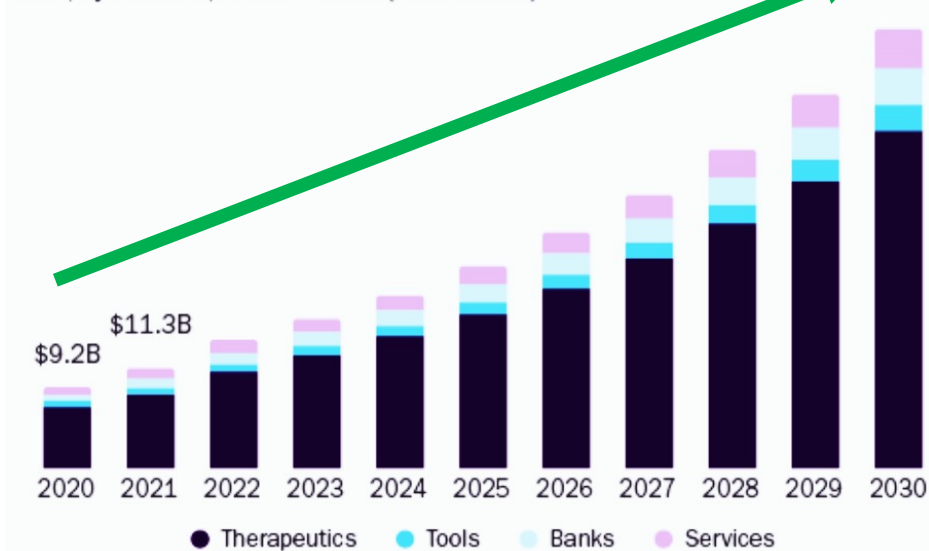
Produced with support from:



Rebuilding
the body

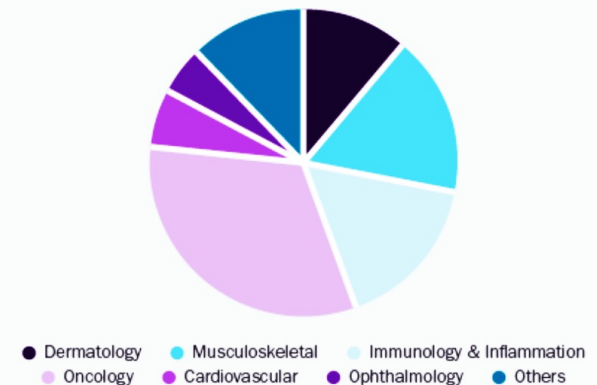
U.S. Regenerative Medicine Market

Size, by Product, 2020 - 2030 (USD Billion)



Global Regenerative Medicine Market

Share, by Therapeutic Category, 2022 (%)

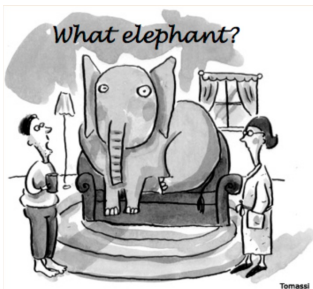


Many Different Disciplines...

High Growth Potential of the RegMed Sector: Herb Brody – Nature 2016

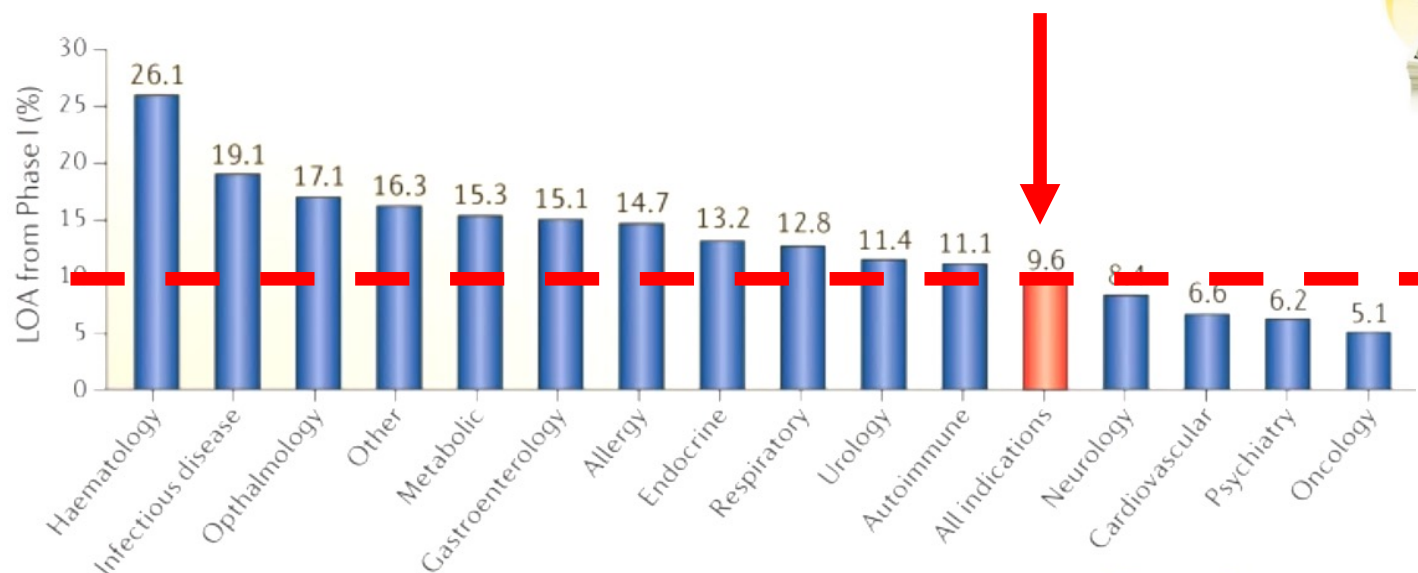
<https://www.grandviewresearch.com/industry-analysis/regenerative-medicine-market#>

Bottleneck: Low LoA for New Therapies



Likelihood of Approval from Phase I <10%

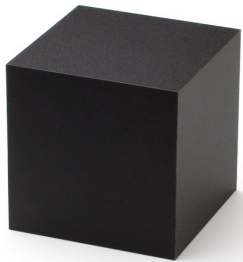
High Failure Rates Adv Clinical Trials >90%



Parsing Clinical Success Rates: Asher Mullard - Nature RevDrugDisc 2016

<https://www.nature.com/articles/nrd.2016.136>

Problem: Neg. Results Rarely Published



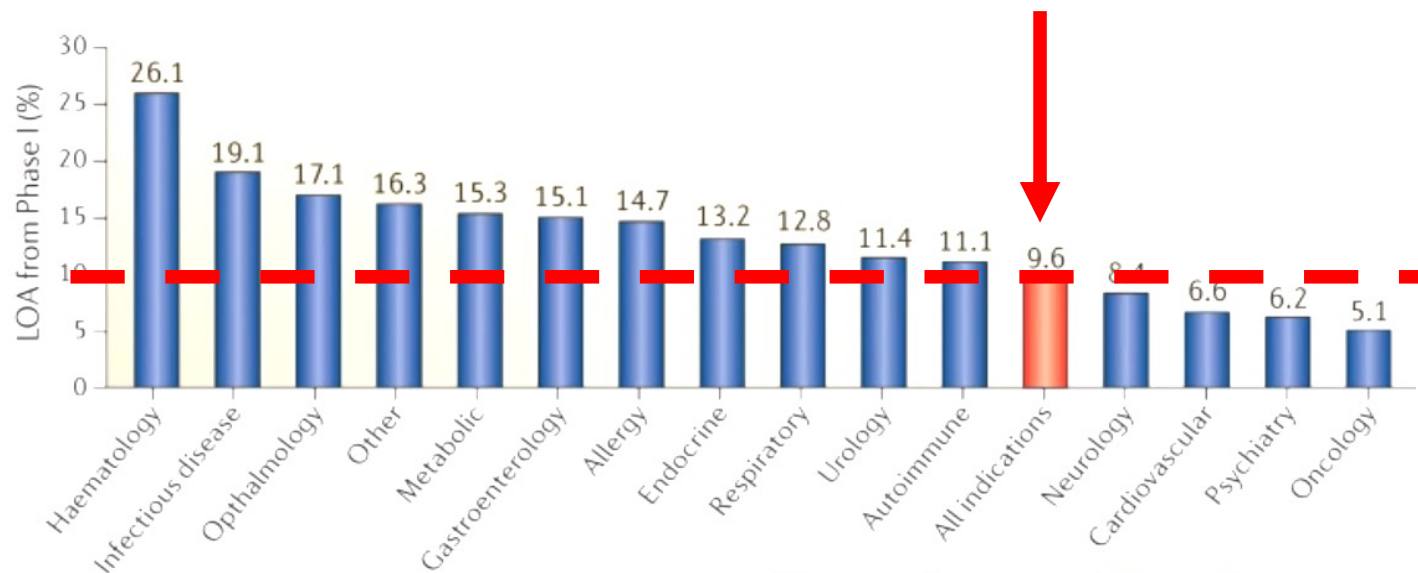
**Few Published
Information on
Failed Trials 90%**



**High Loss in
Translational
Efficacy 90% ?**



**→ Waste of Resources!
→ Few Learning Outcomes!
→ Delayed Access to New Therapies!**

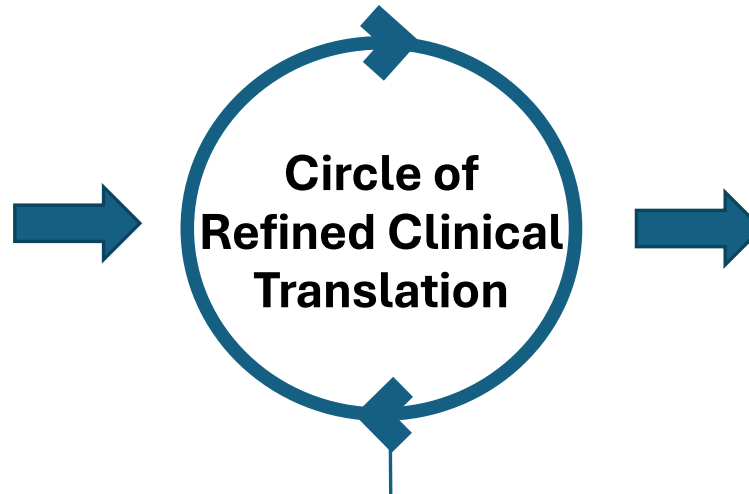


Parsing Clinical Success Rates: Asher Mullard - Nature RevDrugDisc 2016

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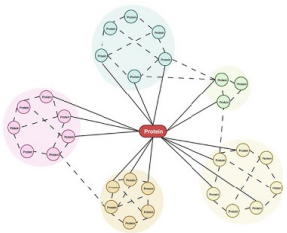
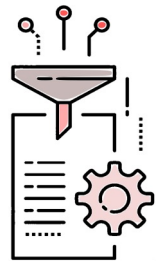
Solution: Refined Clinical Translation (1-3)

**Insufficient Performance
with Conventional
Approaches...**



**Faster and More
Efficient Access to
Novel Therapies!**

Suitable Networks, Infrastructure, Resources



**RCT1: Better Use Open Data +
Advanced Data Analysis Tools**

**RCT2: Improved Trial Design
with Iterative Adjustments**

**RCT3: Biomedical Engineering
Product Properties / Delivery**

Otávio Cabral-Marques & Guido Moll in *Autoimmunity Reviews* 2022

<https://www.sciencedirect.com/science/article/pii/S1568997223000447?via%3Dihub>



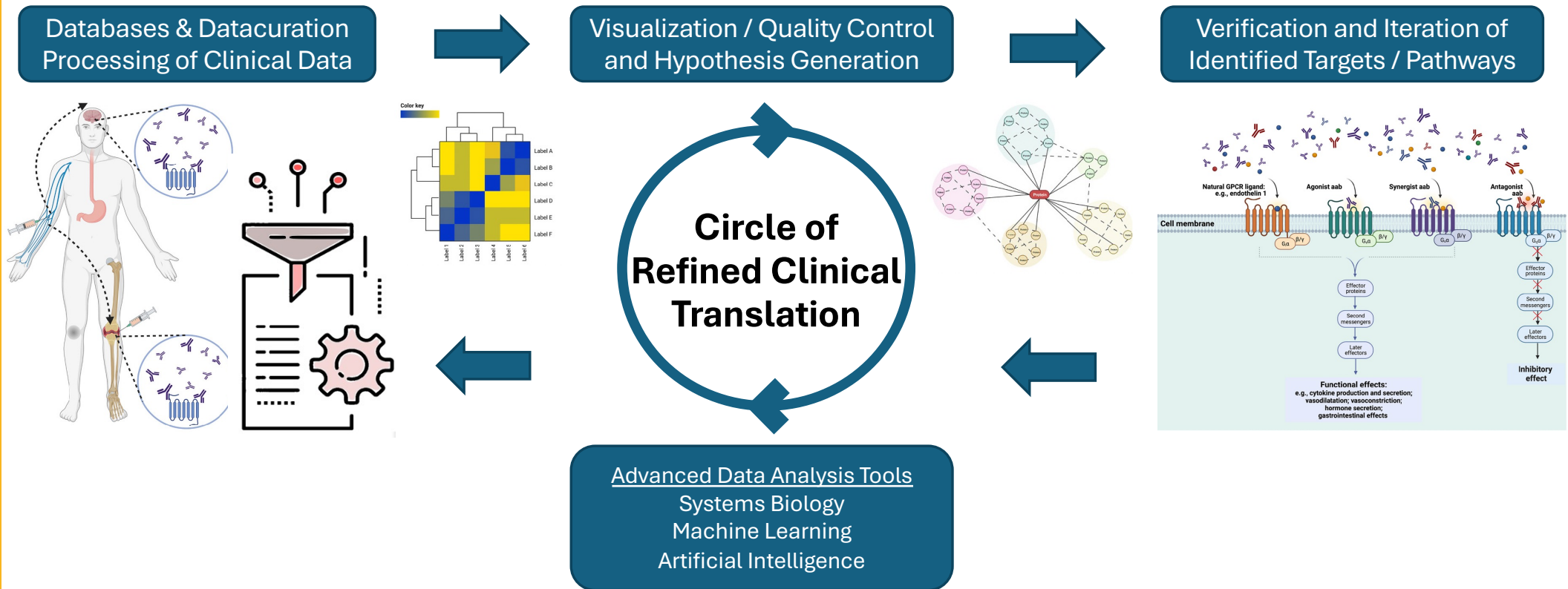
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RCT1: Better Use of OpenData and ADATs



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Otávio Cabral-Marques & Guido Moll in *Autoimmunity Reviews* 2022

<https://www.sciencedirect.com/science/article/pii/S1568997223000447?via%3Dihub>



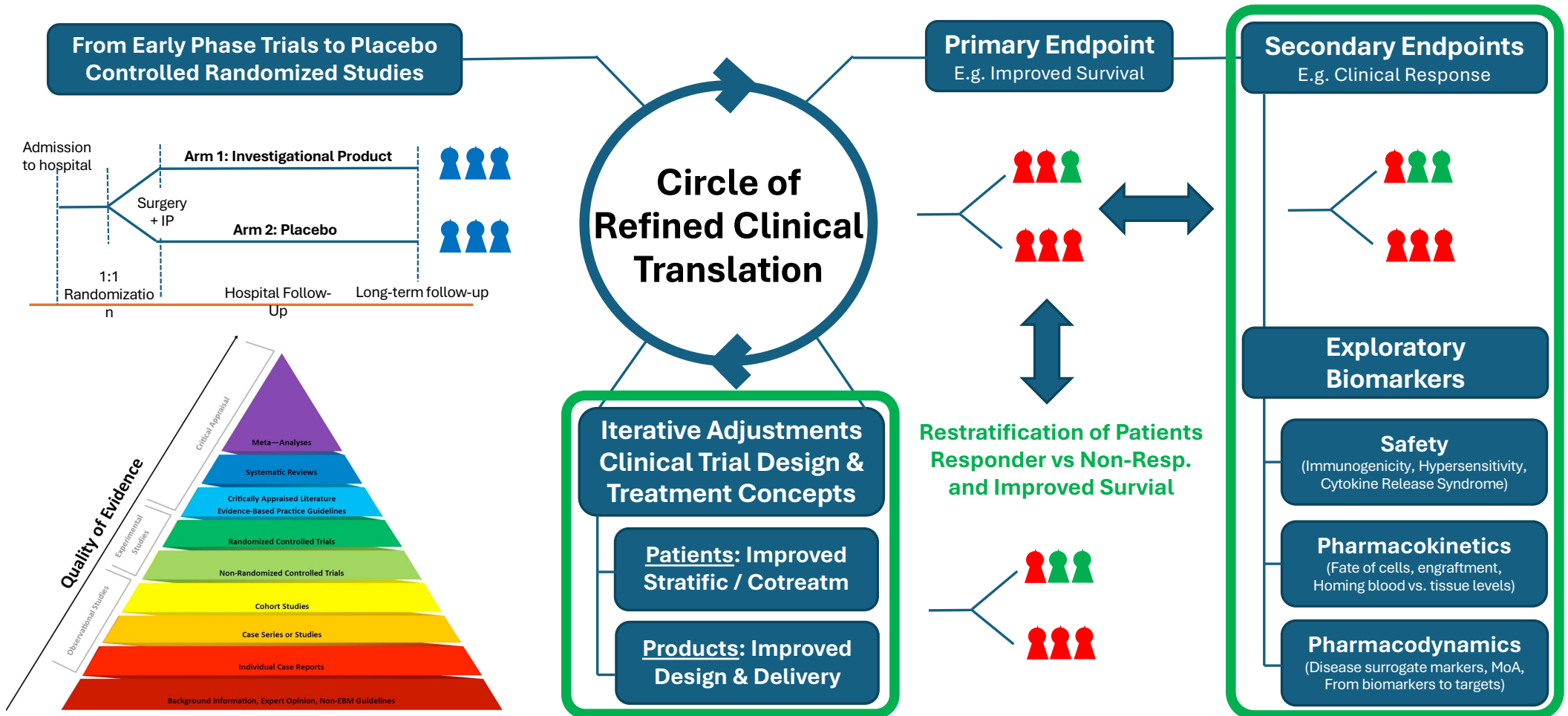
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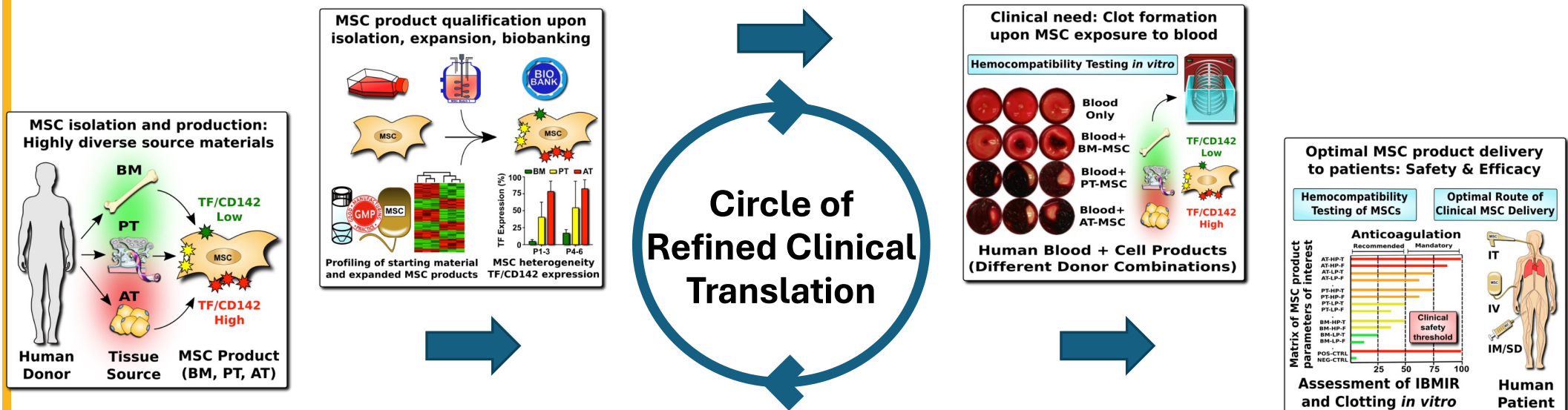
RCT2: Better Trials (Patients & Products)



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RCT3: Engineering (Products & Delivery)



Guido Moll & James Ankrum & Hans-Dieter Volk & Petra Reinke et al. TMM 2019 –
Intravascular MSC Therapy Product Diversification: Time for New Clinical Guidelines!

Guido Moll & Norman Drzeniek & Sven Geissler & Hans-Dieter Volk & Petra Reinke et al. FIM 2020 – **MSC Therapies for Covid-19: Importance of Patient Coagulopathy, Thromboprophylaxis, Cell Product Quality & Mode of Delivery for Treatment Safety & Efficacy**

Guido Moll & James Ankrum & Scott Olson & Jan Nolte et al. SCTM 2022 – **Improved MSC Minimal Criteria to Maximize Patient Safety: A Call to Embrace Tissue Factor and Hemocompatibility Assessment of MSC Products**

<https://parentsguidecordblood.org/en/news/therapeutic-msc-infusions-when-more-good-thing-not-always-better>

The global evolution and impact of systems biology and artificial intelligence in stem cell research and therapeutics development: a scoping review

Thayna Silva-Sousa^{1,2,3,4,†}, Júlia Nakanishi Usuda^{1,2,3,4,5,†}, Nada Al-Arawe^{1,2,3,4,6,7,†}, Francisca Frias^{1,2,3,4}, Irene Hinterseher^{3,4,8}, Rusan Catar⁶, Christian Luecht⁶, Katarina Riesner⁷, Alexander Hackel⁹, Lena F. Schimke¹⁰, Haroldo Dutra Dias¹¹, Igor Salerno Filgueiras¹⁰, Helder I. Nakaya^{5,12}, Niels Olsen Saraiva Camara⁵, Stefan Fischer⁹, Gabriela Riemekasten⁹, Olle Ringdén¹³, Olaf Penack⁷, Tobias Winkler^{1,2}, Georg Duda^{1,2}, Dennyson Leandro M. Fonseca^{1,2,11,†}, Otávio Cabral-Marques^{5,10,11,12,14,†}, Guido Moll^{1,2,6,†,✉}

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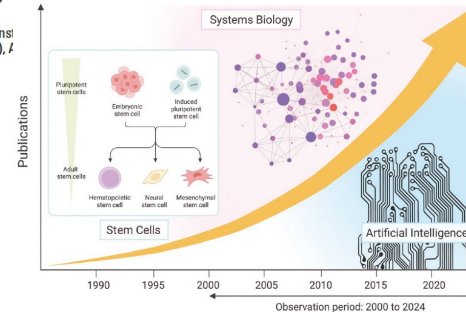
¹⁴D'OR Institute Research and Education, SP, Brazil

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Article



<https://doi.org/10.1038/s41540-025-00488-z>

Dysregulated autoantibodies targeting AGTR1 are associated with the accumulation of COVID-19 symptoms

Check for updates

Dennyson Leandro M. Fonseca^{1,2}✉, Maj Jäpel³, Michael Adu Gyamfi⁴, Igor Salerno Filgueiras⁵, Gabriela Crispim Baiochi⁶, Yuri Ostrinski^{6,7}, Gilad Halpert^{7,8}, Yael Bublil Lavi⁹, Elroy Vojdani¹⁰, Thayna Silva-Sousa^{11,12}, Júlia Nakanishi Usuda^{12,13}, Juan Carlo Santos e Silva¹³, Paula P. Freire¹³, Adriel Leal Nóbile¹³, Anny Silva Adri¹³, Pedro Marçal Barcelos¹³, Yohan Lucas Gonçalves Corrêa¹³, Fernando Yuri Nery do Vale¹³, Leticia Oliveira Lopes¹³, Solveig Lea Schmidt⁸, Xiaoqing Wang¹⁴, Carl Vahldieck^{15,16}, Benedikt Fels^{15,16}, Lena F. Schimke⁵, Gustavo Cabral-Miranda⁵, Mario Hiroyuki Hirata¹³, Taj Ali Akhan^{17,18}, Yen-Rei A. Yu¹⁹, Rodrigo JS Dalmolin^{20,21}, Howard Amital⁸, Aristo Vojdani²², Haroldo Dutra Dias²³, Helder Nakaya^{13,24}, Hans D. Ochs²⁵, Jonathan I. Silverberg²⁶, Jason Zimmerman²⁷, Israel Zyskind^{27,28}, Avi Z. Rosenberg²⁹, Kai Schulze-Forster³⁰, Harald Heidecke³⁰, Rusan Catar^{4,35}, Guido Moll^{1,4,35}, Alexander Hackel^{3,35}, Kristina Kusche-Vihrog^{15,16,35}, Yehuda Shoenfeld^{7,8,21,35}, Gabriela Riemekasten^{3,35}, Reza Akbarzadeh^{3,35}✉, Alexandre H. C. Marques^{20,35} & Otavio Cabral-Marques^{1,3,8,32,33,34,35}✉



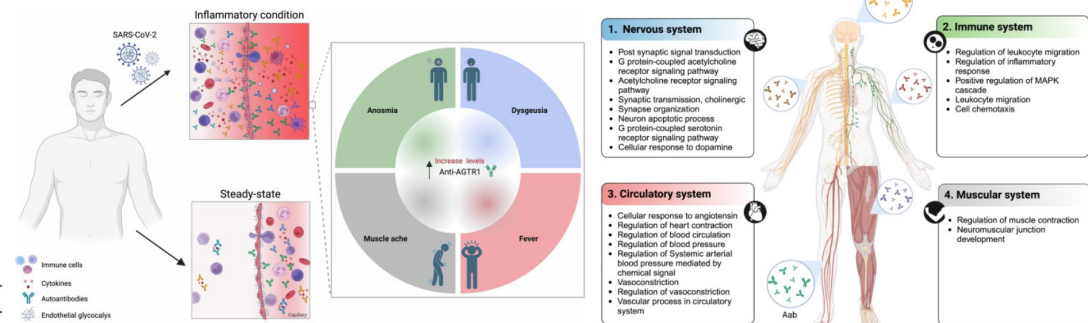
D.Fonseca



T.Sousa



J.Usuda





March 25-26th, 2025

Thank You....



BIH Regeneration
BIH Center for Regenerative Therapies (BCRT)



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SFB CRC 1365 – Renoprotection**

