

# Effective clinical trial collaboration: the Janssen perspective

Tobias Kampfenkel, MD, MHBA

*Medical Director, Janssen, Late Clinical Development*

*Disclosures: Employee of Janssen*



# Why do we need to collaborate?

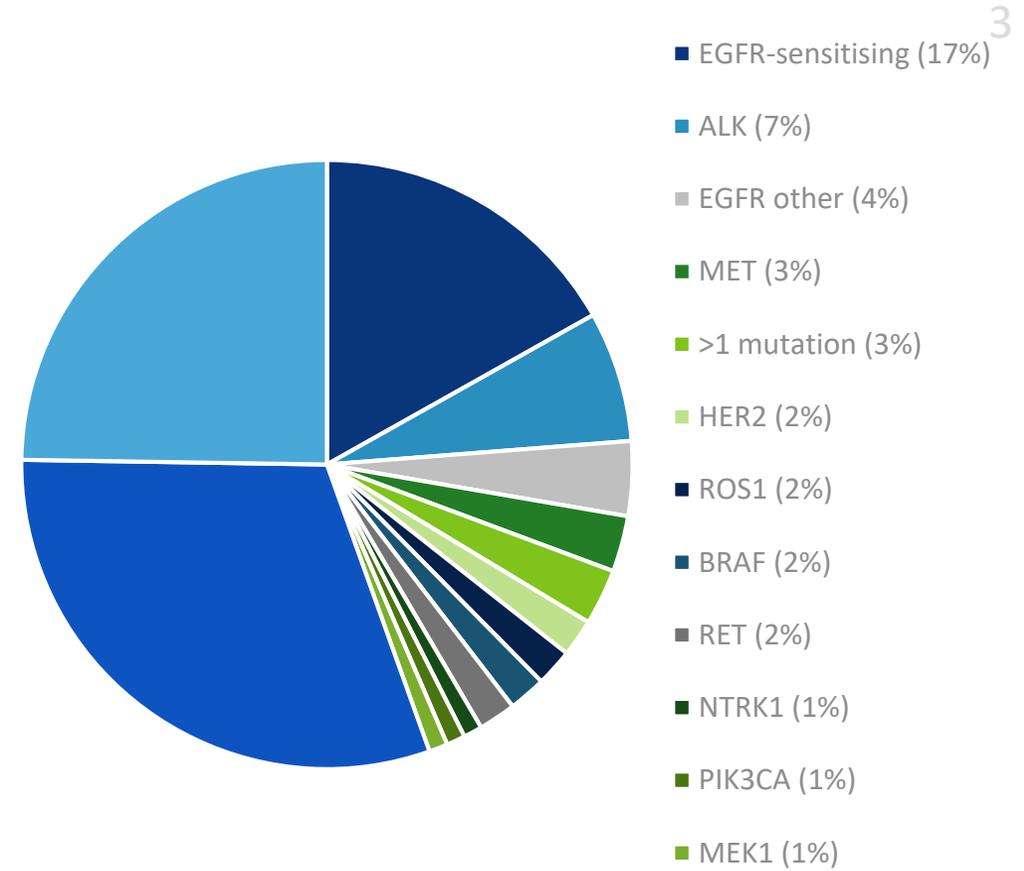
1 410 000<sup>1</sup>

Deep Learning

ICH-GCP

10/year<sup>2</sup>

Big Data



# Janssen: >30 Years of Innovation in Oncology



# The Janssen perspective on collaboration

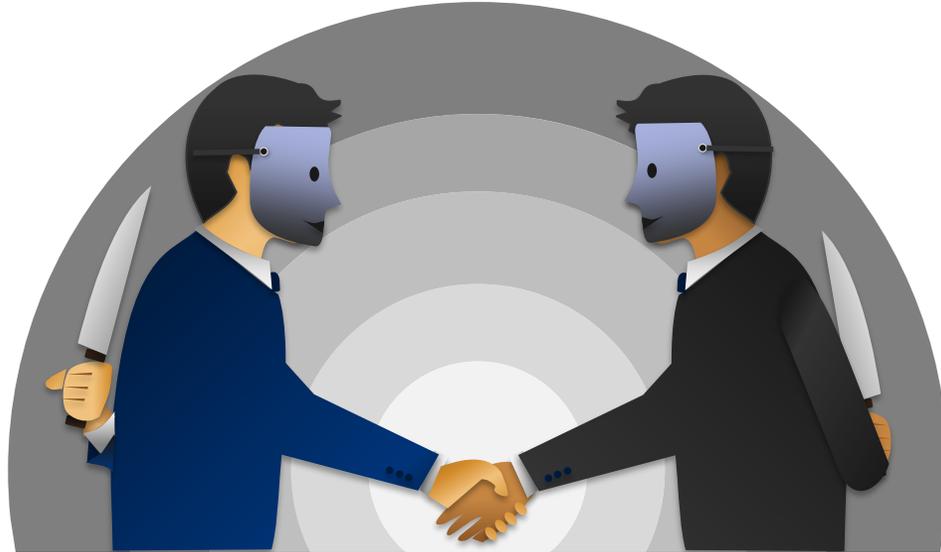


**LET'S TALK!**

[WWW.JNJINNOVATION.COM](http://WWW.JNJINNOVATION.COM)

- Innovation Centers
- Johnson & Johnson INNOVATION - JLABS -
- Johnson & Johnson INNOVATION - JANSSEN BUSINESS DEVELOPMENT -

# Collaboration?



**Traitorous cooperation  
with the enemy**

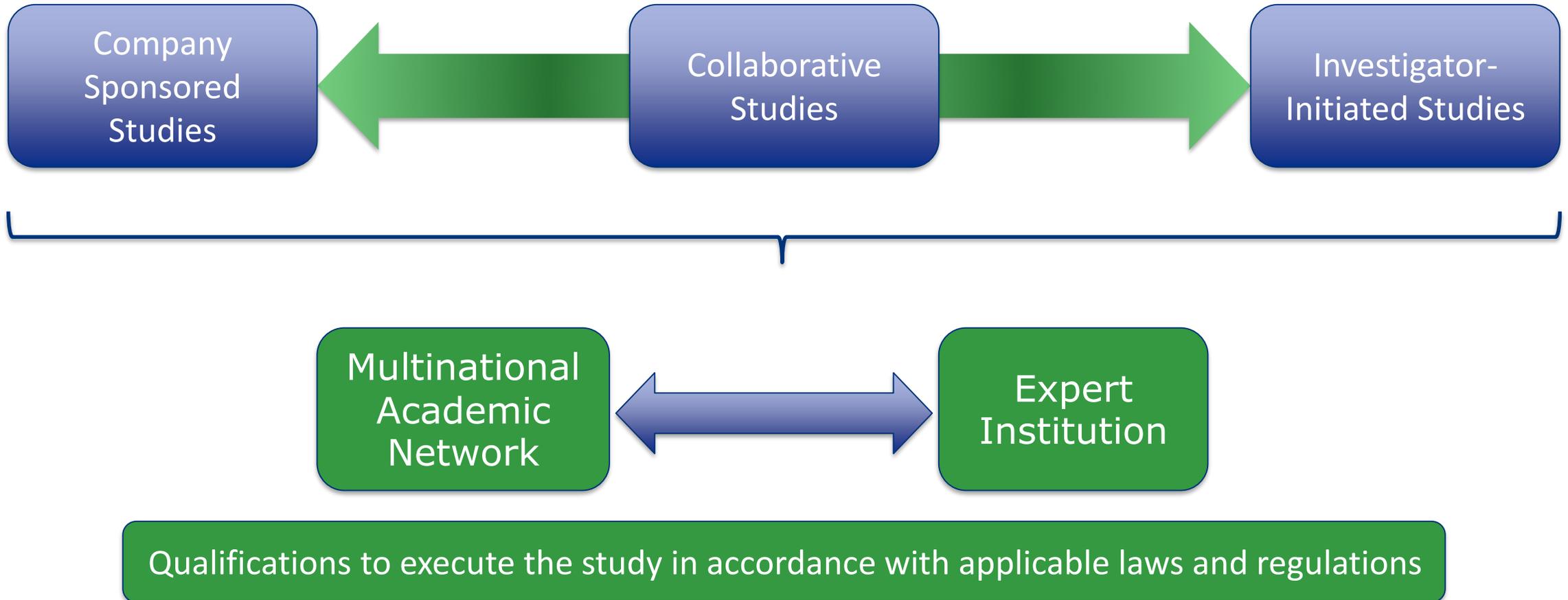


**The action of working with  
someone to produce something**

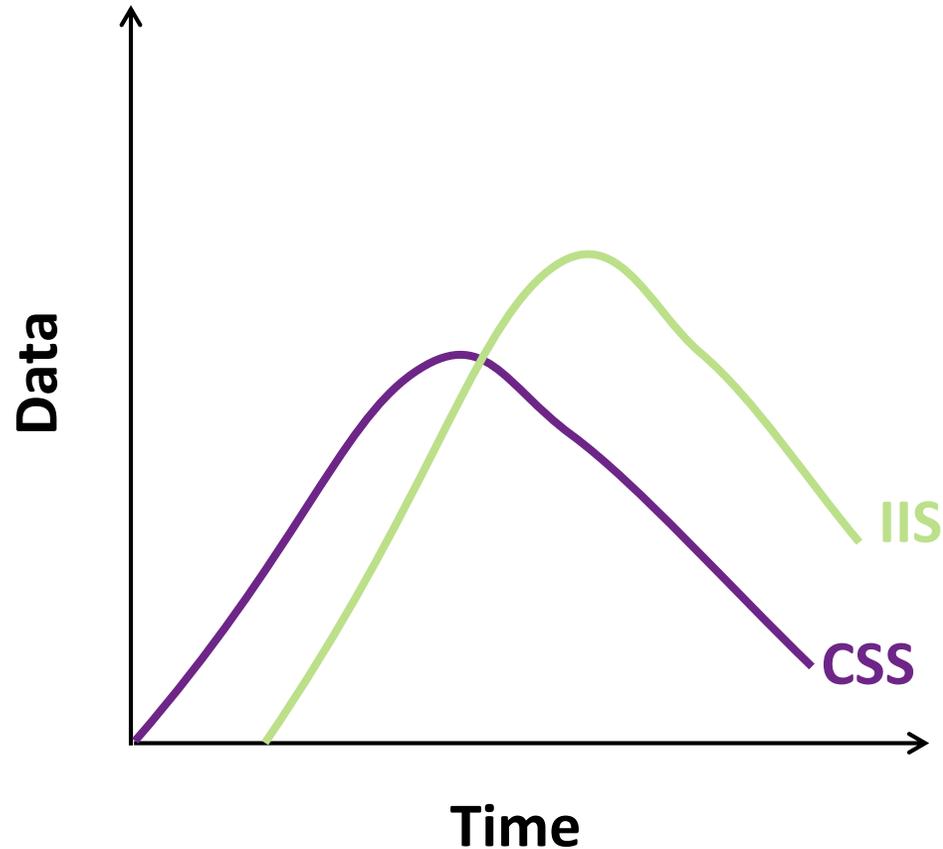
# Collaboration on clinical trials: a continuum of models



# Who is our preferred partner for collaboration?



# Investigator-initiated studies: a critical part of data generation to meet all patient's needs



[www.JanssenOnclIS.com](http://www.JanssenOnclIS.com)

**Welcome to the Janssen Oncology & Haematology Investigator-Initiated Studies Website**

**Mission Statement**

The Janssen Oncology and Haematology Investigator-Initiated Study (IIS) program is aimed at advancing scientific knowledge through the support of unique research proposals from independent investigators.

**IIS Program**

This global program is open to all researchers who are interested in conducting their own research. Support may be provided in the form of funding and/or product. Financial and/or product support is contingent upon full execution by both parties of a research agreement.

**Types of research considered for support**

- Interventional studies
- Retrospective data reviews
- Registries
- Outcomes research
- Epidemiology studies
- Non-Clinical studies

Submission of an IIS application to Janssen does not imply or guarantee approval.

[Click here for more information on our IIS program](#)

[Submit an Application:](#)

IIS: investigator-initiated studies; CSS: company-sponsored studies

# Why do we do clinical research beyond CSS?

Advance Science beyond  
Core Development Plan

Local Data Needs

Translational Research

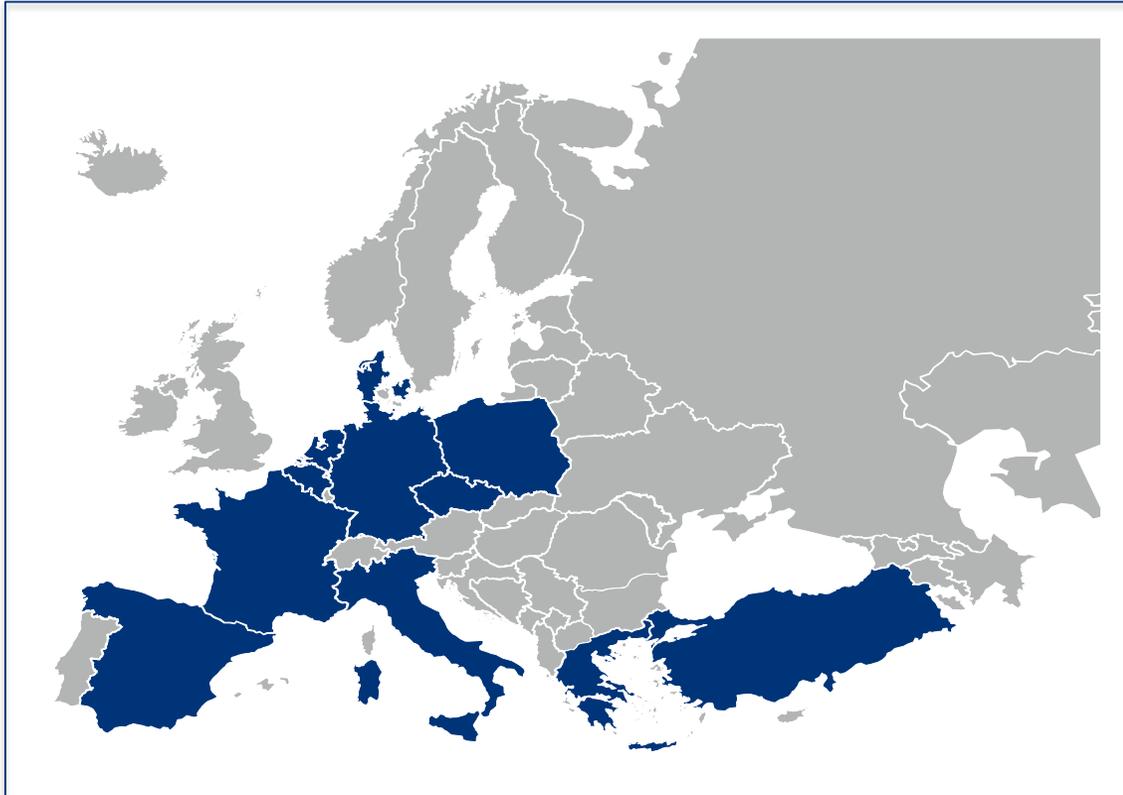
Networks and  
Infrastructure

Knowledge and  
Experience

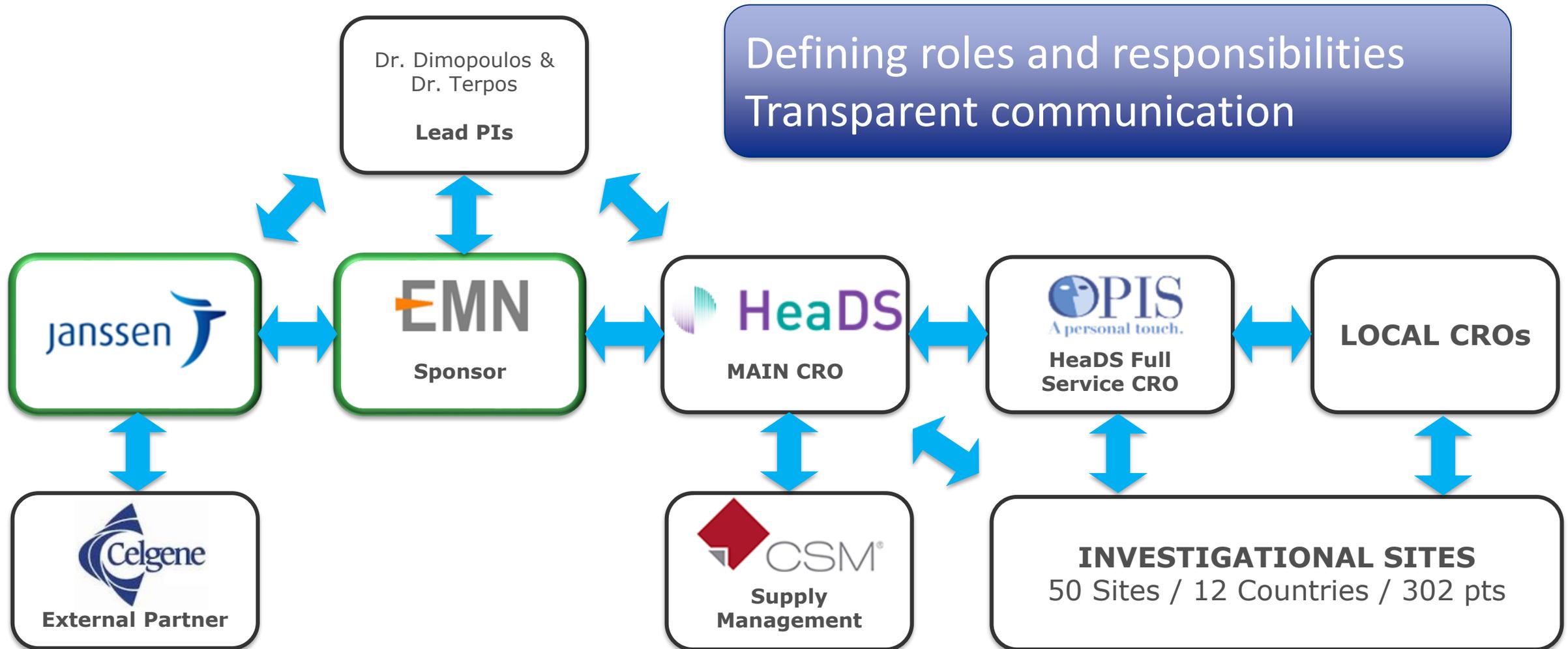


# APOLLO: Pom-Dex ± Daratumumab in Patients with RRMM: a Multicenter, Randomized, Phase 3 Study

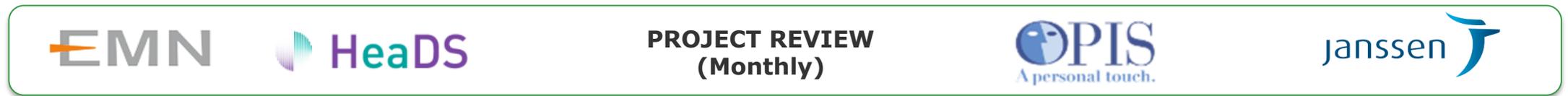
Countries involved in the APOLLO study



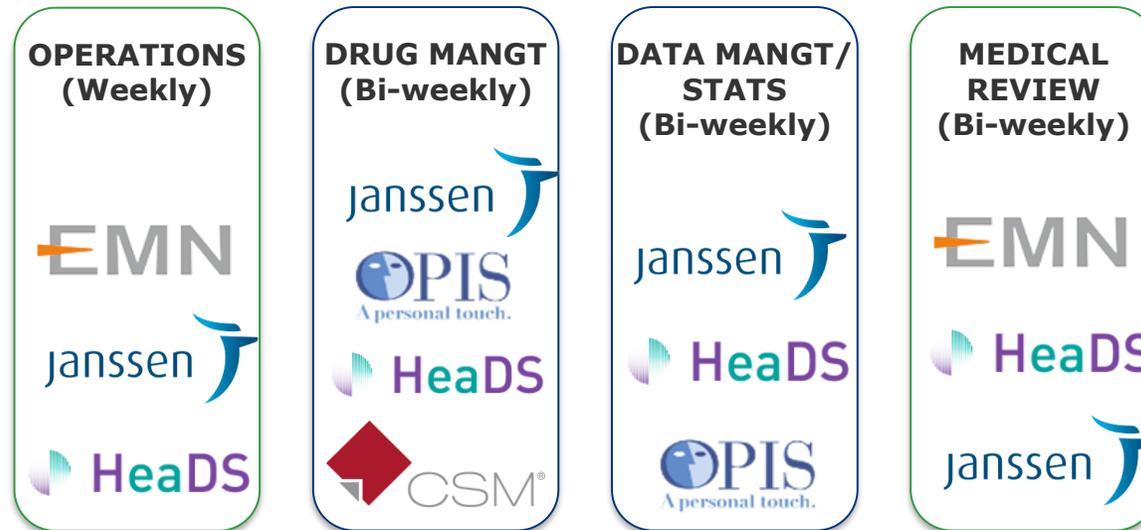
# APOLLO: Complexity of collaboration in clinical research



# APOLLO: A clear plan for communication is key



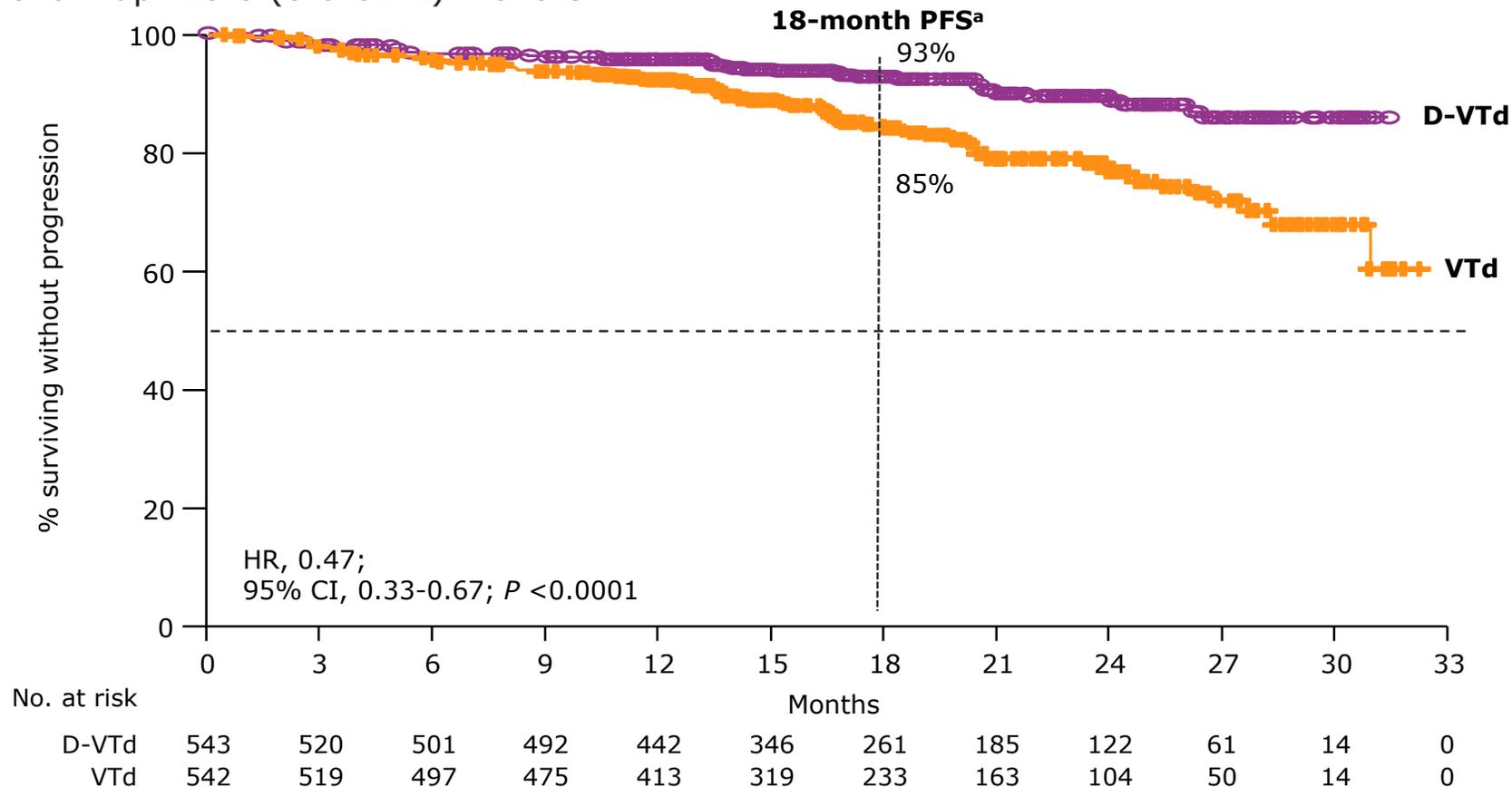
## FUNCTIONAL MEETINGS:



# CASSIOPEIA: Daratumumab-VTd vs VTd before and after transplant in NDMM



- Median (range) follow-up: 18.8 (0.0-32.2) months



**53% reduction in the risk of progression or death in patients receiving D-VTd**

HR, hazard ratio;  
CI, confidence interval.  
<sup>a</sup>Kaplan-Meier estimate.

# What are challenges for collaboration in clinical research?

Roles and Responsibilities

Communication

Resourcing  
Contracting  
Timelines

GCP / Quality

Independence



# The foundations of successful collaboration



1930

1940

1950

1960

1970

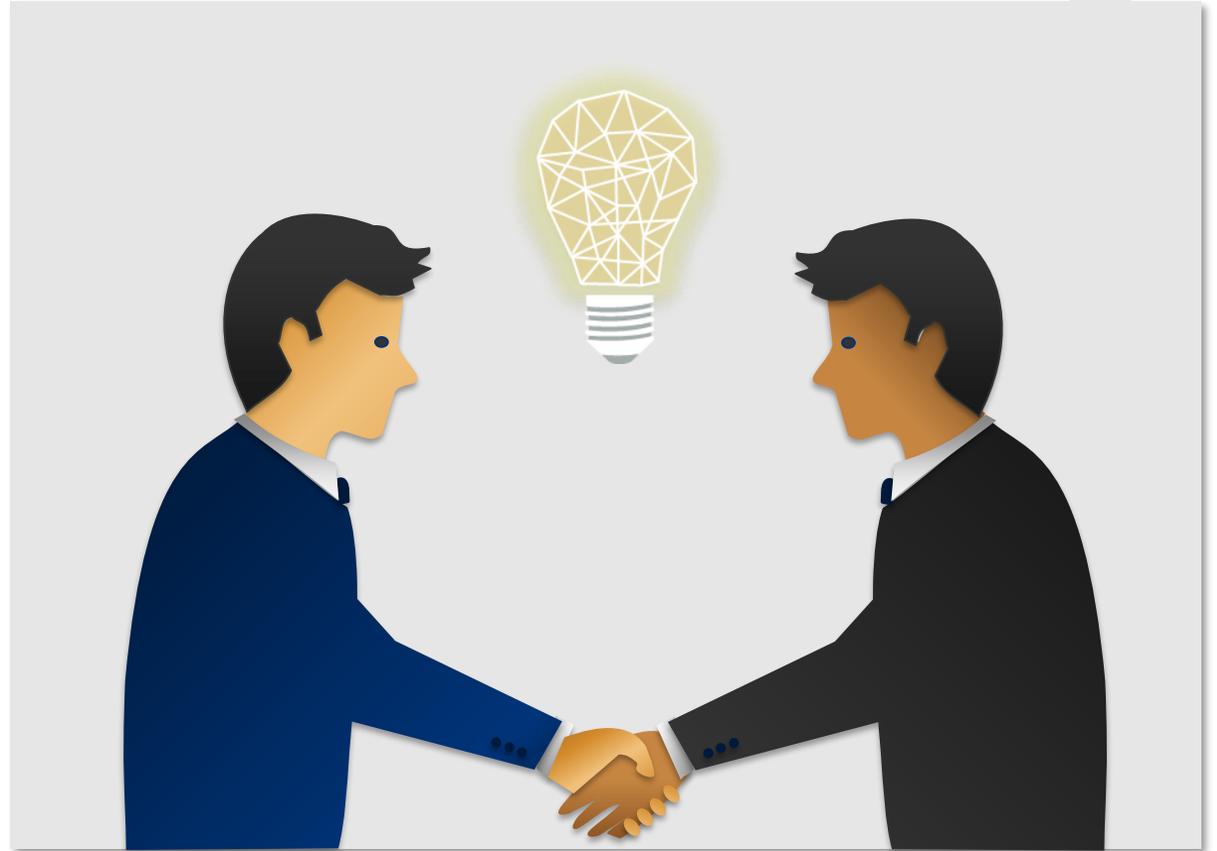
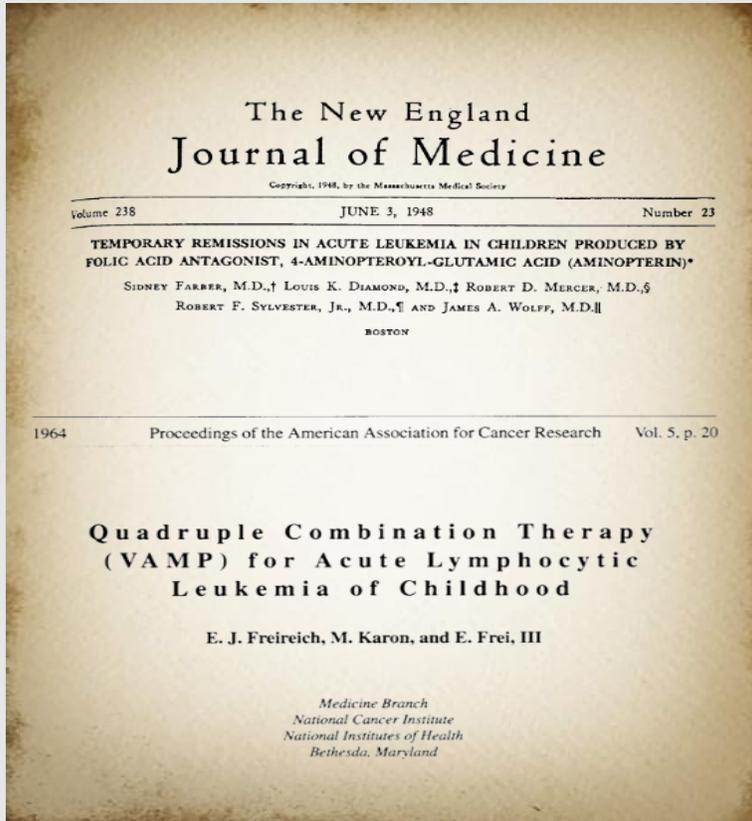
1980

1990

2000

2010

2020





**Thank you for your attention!**