

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?

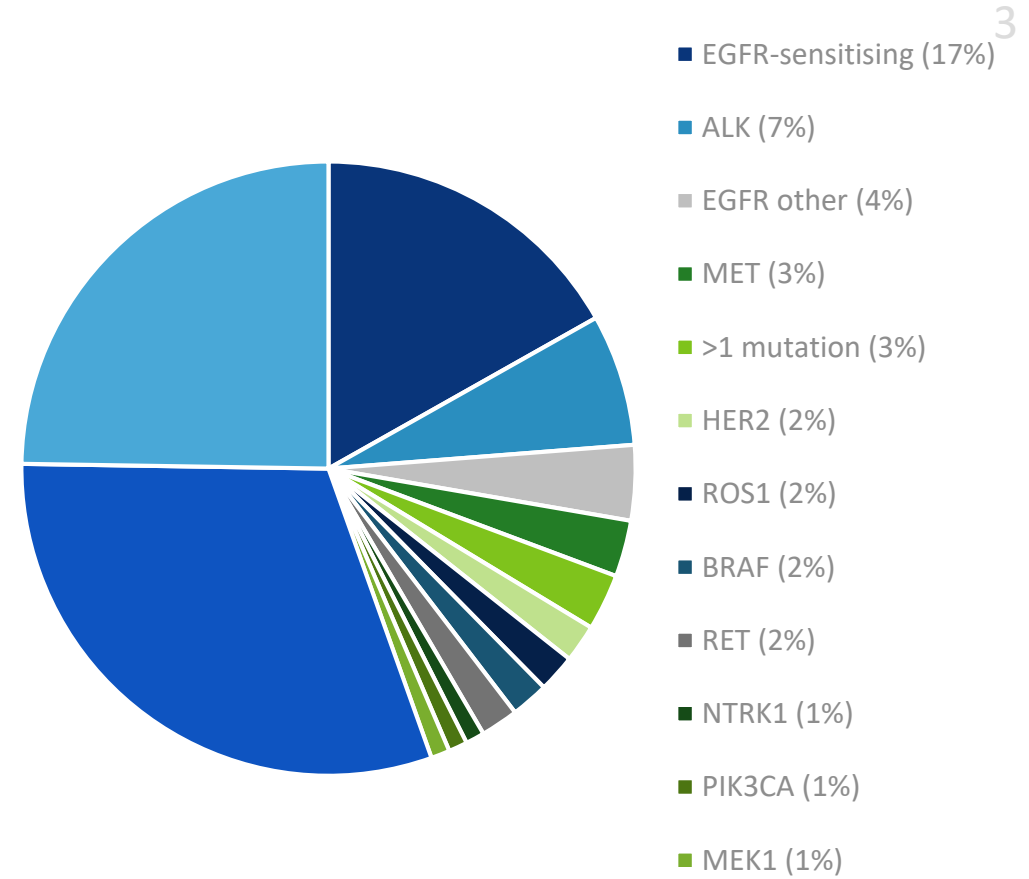
1 410 000¹

Deep Learning

ICH-GCP

10/year²

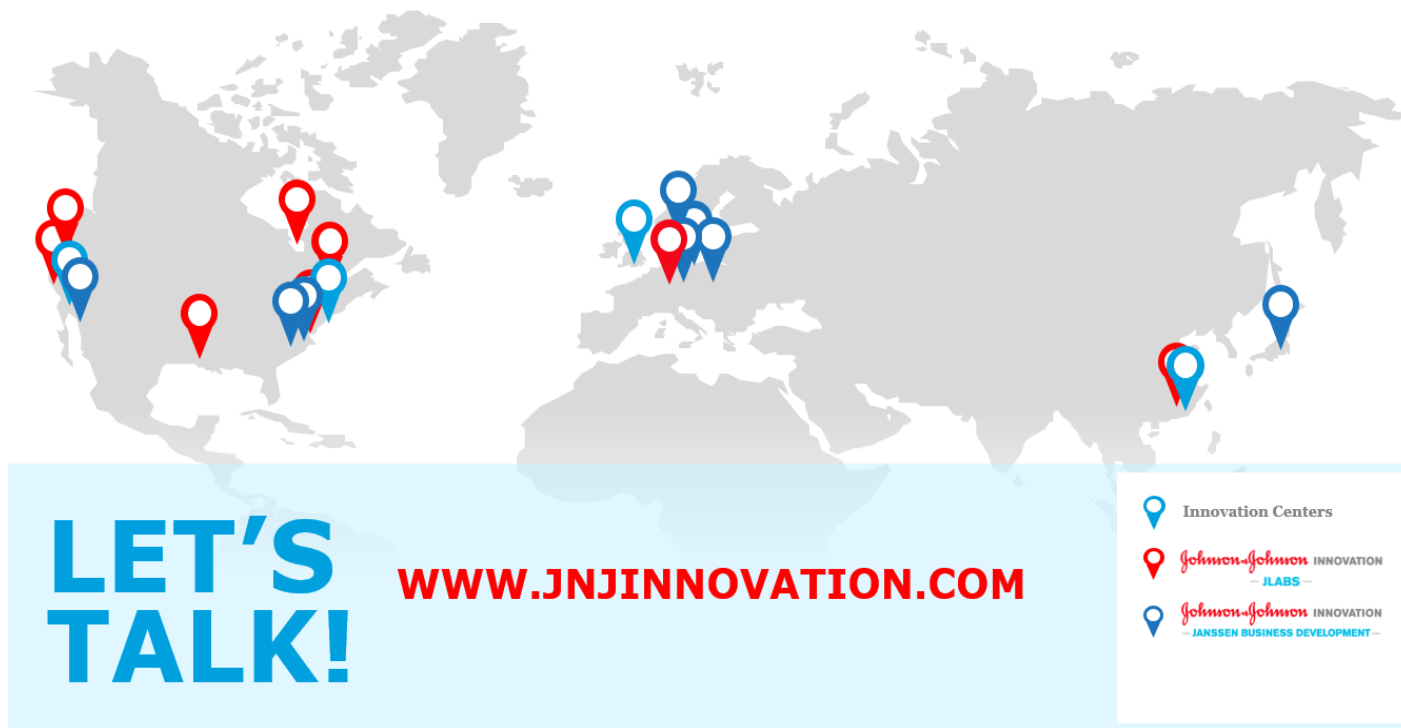
Big Data



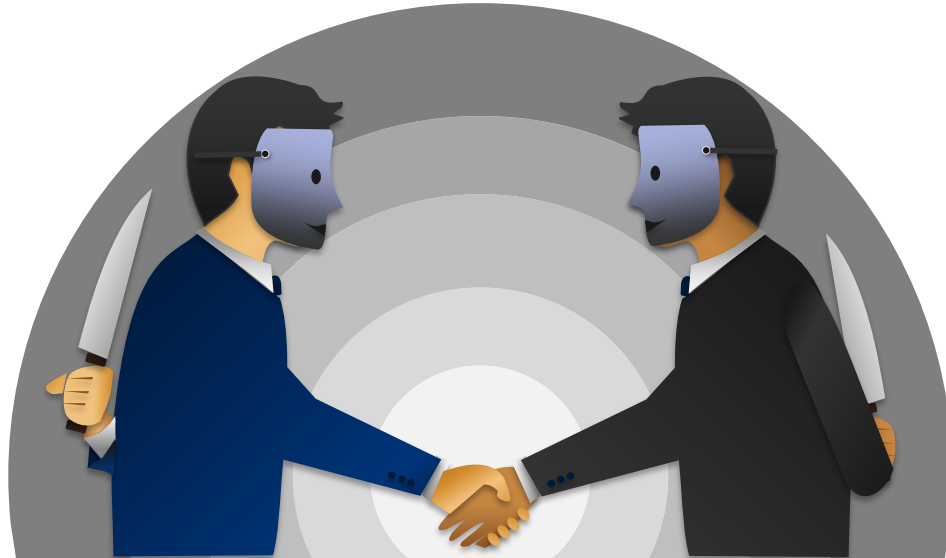
Janssen: >30 Years of Innovation in Oncology



The Janssen perspective on collaboration



Collaboration?



**Traitorous cooperation
with the enemy**

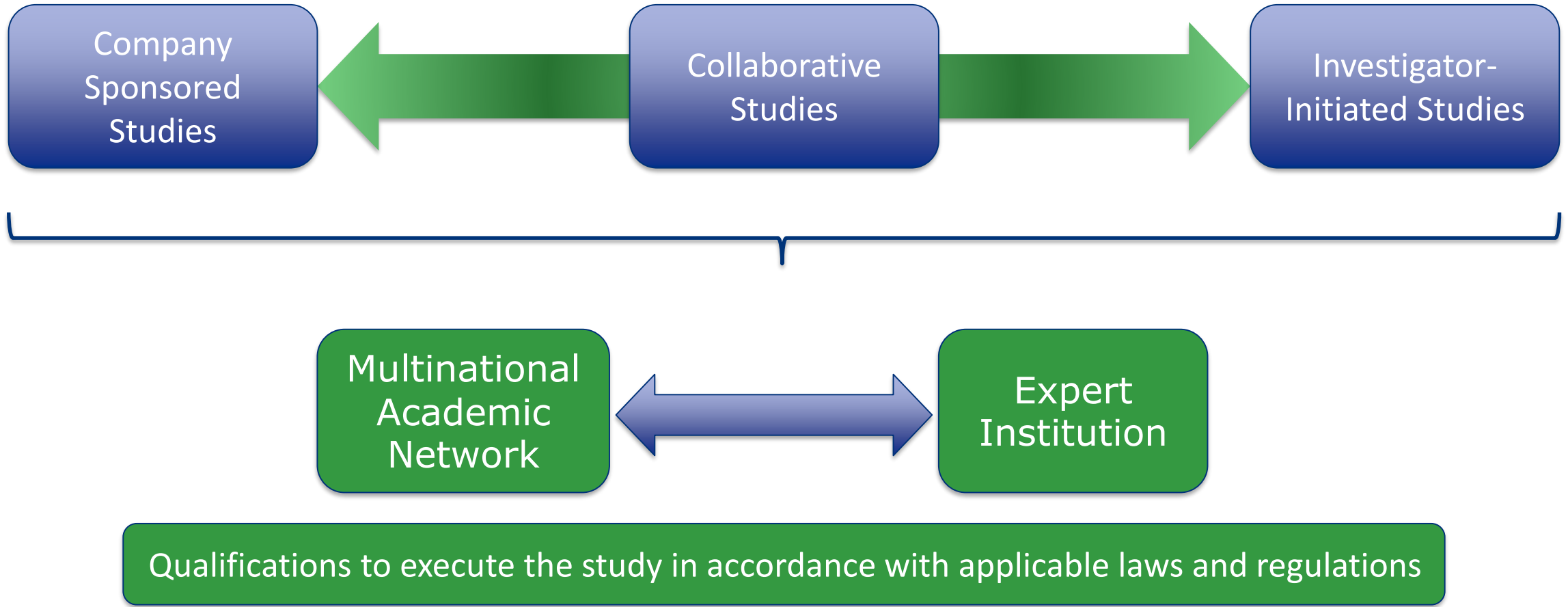


**The action of working with
someone to produce something**

Collaboration on clinical trials: a continuum of models

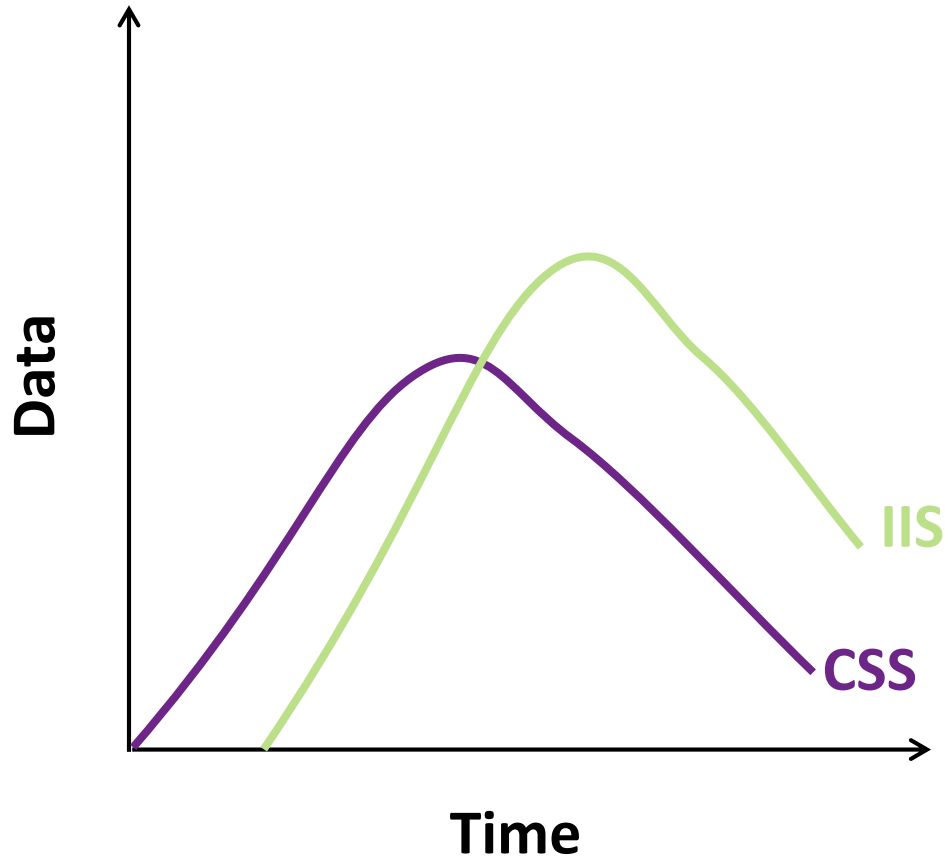


Who is our preferred partner for collaboration?



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

www.JanssenOncIIS.com



The screenshot shows the homepage of the Janssen Oncology & Haematology Investigator-Initiated Studies Website. The header includes a navigation bar with 'Login' and 'Create New Account' links. The main content area features a welcome message, a mission statement, and details about the IIS program. A sidebar on the right includes a photo of a woman and a button to 'Click here for more information on our IIS program'. The footer contains a 'Submit an Application:' link.

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

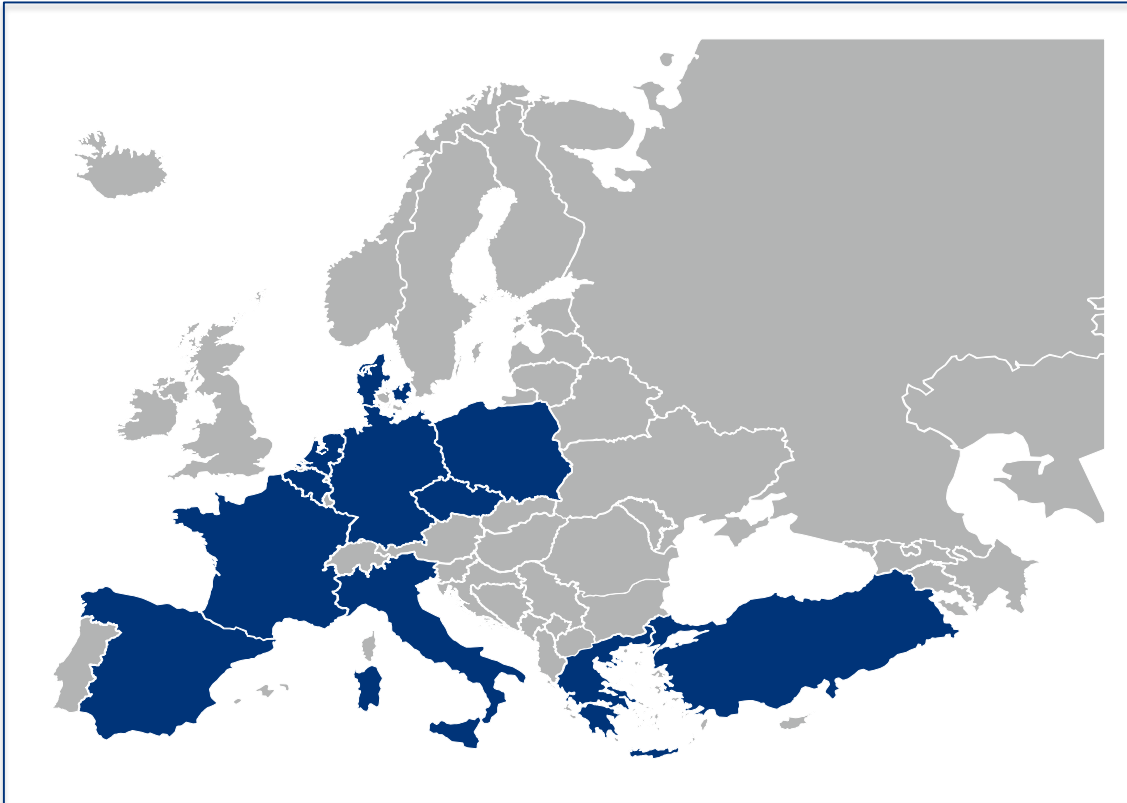
Networks and
Infrastructure

Knowledge and
Experience

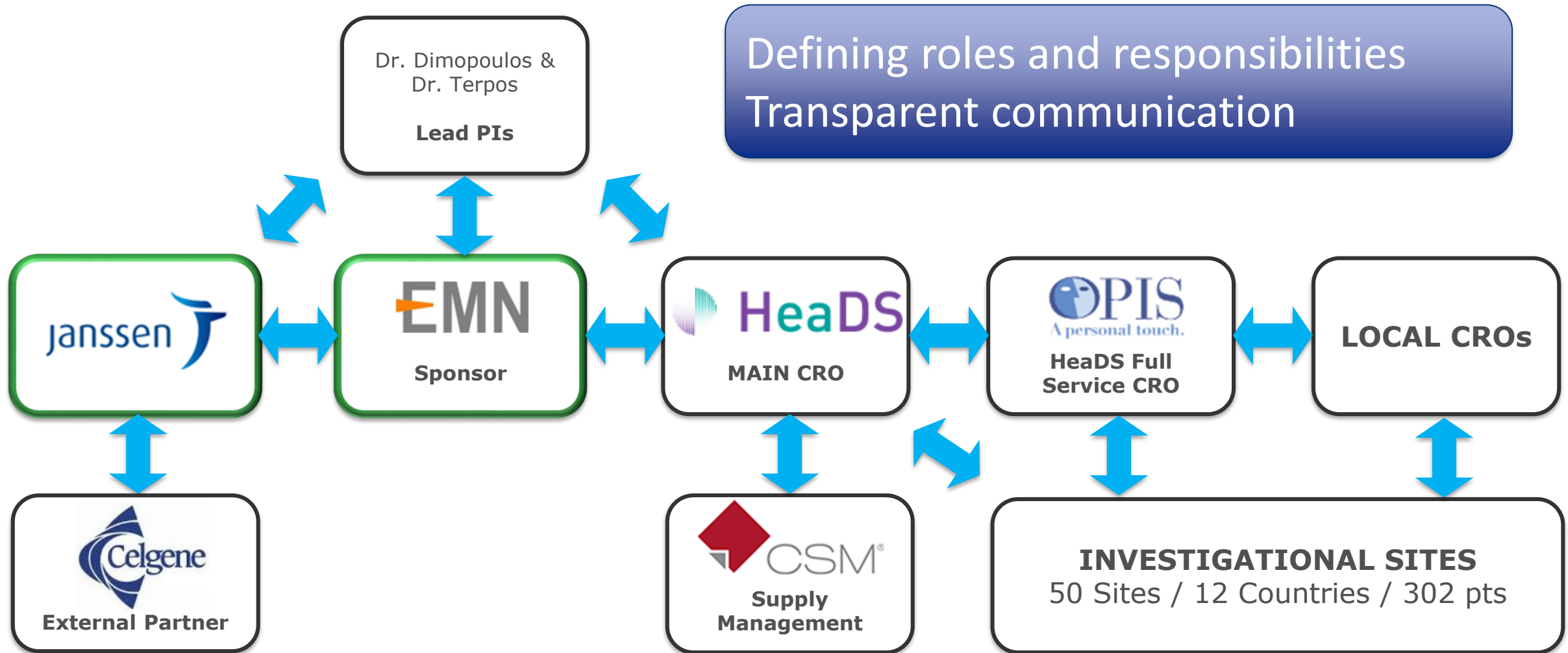


APOLLO: Pom-Dex ± Daratumumab in Patients with RRMM: a Multicenter, Randomized, Phase 3 Study

Countries involved in the APOLLO study



APOLLO: Complexity of collaboration in clinical research



APOLLO: A clear plan for communication is key

EMN

JOINT STEERING COMMITTEE

janssen 

EMN

 **HeaDS**

**PROJECT REVIEW
(Monthly)**

 **OPIS**
A personal touch.

janssen 

FUNCTIONAL MEETINGS:

**OPERATIONS
(Weekly)**

EMN

janssen 

 **HeaDS**

**DRUG MANGT
(Bi-weekly)**

janssen 

 **OPIS**
A personal touch.

 **HeaDS**

 **CSM**[®]

**DATA MANGT/
STATS
(Bi-weekly)**

janssen 

 **HeaDS**

 **OPIS**
A personal touch.

**MEDICAL
REVIEW
(Bi-weekly)**

EMN

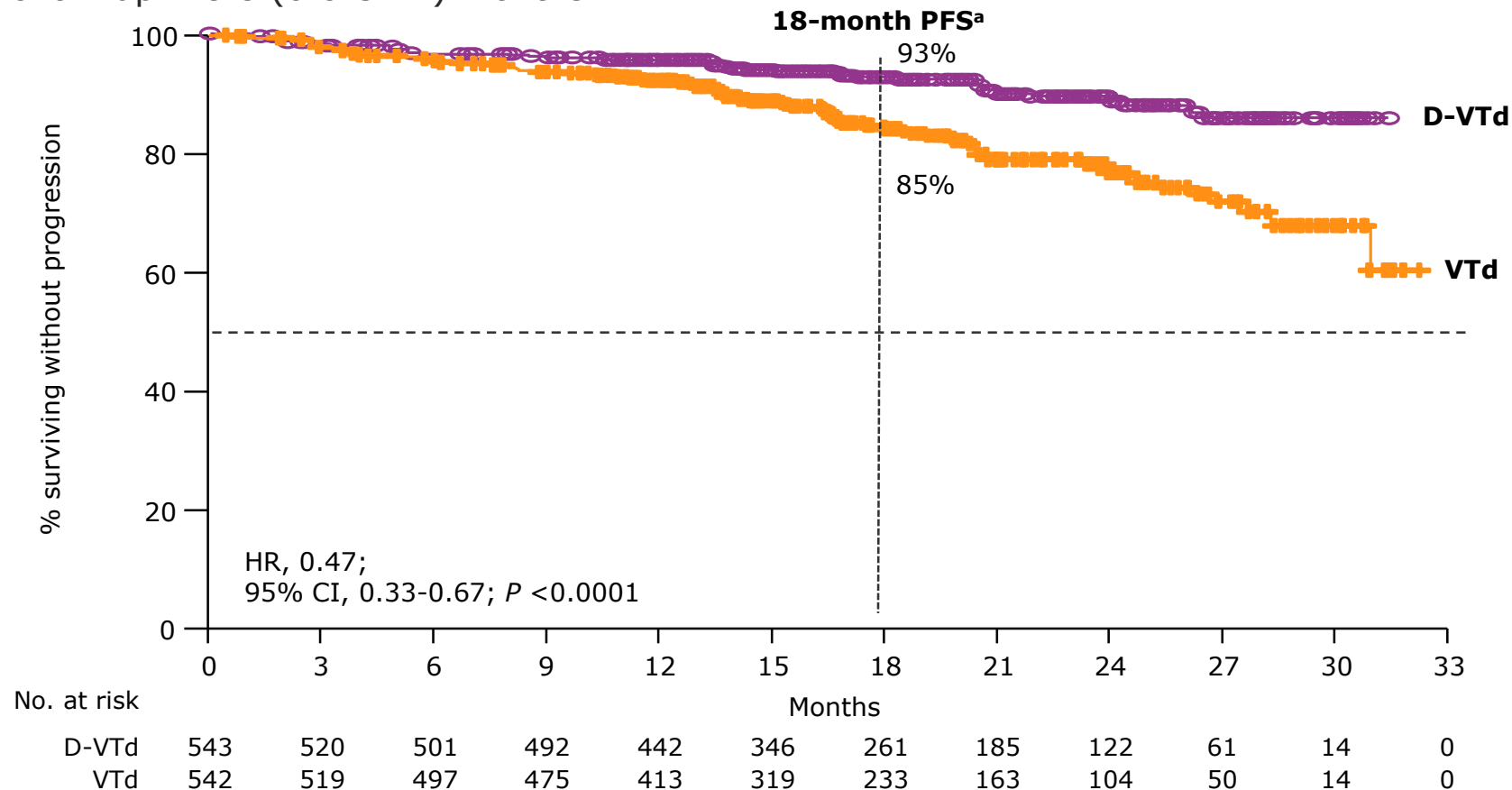
 **HeaDS**

janssen 

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

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

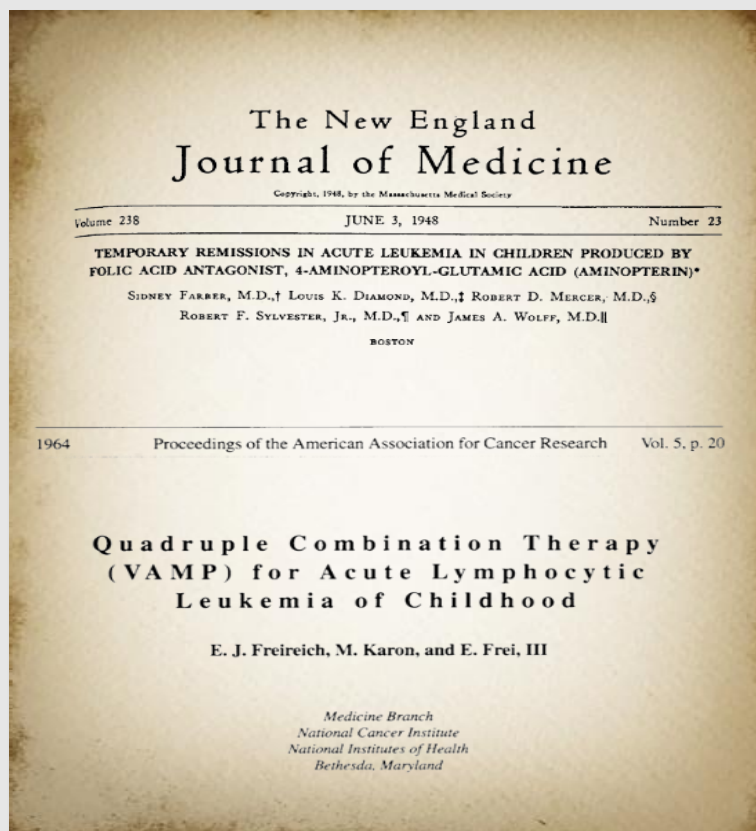
1980

1990

2000

2010

2020





Thank you for your attention!