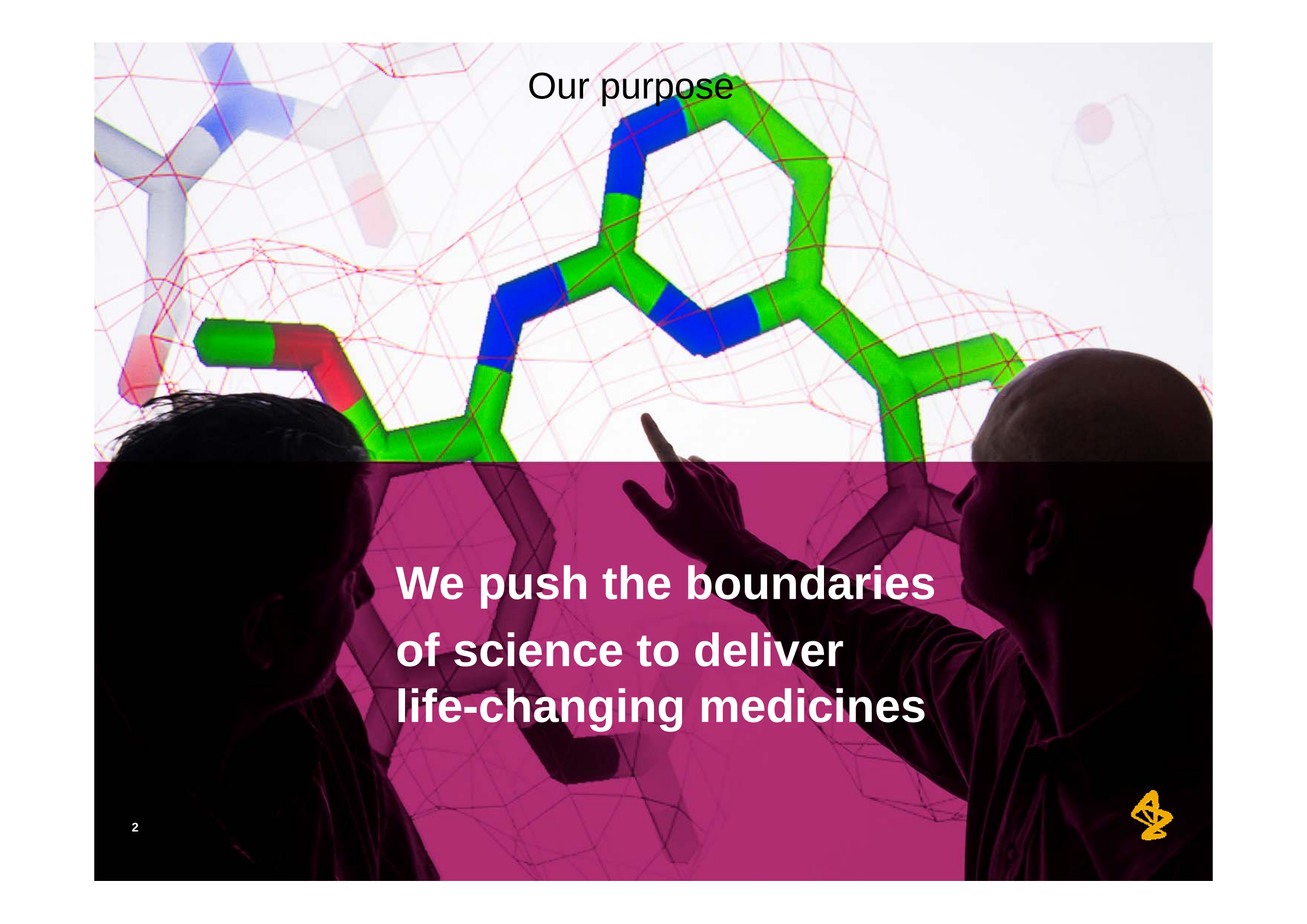

Understanding Trial Design using Visualization

Maria Benjegård and Kerstin Forsberg
Phuse Vienna October 2015





Our purpose

**We push the boundaries
of science to deliver
life-changing medicines**



Our Global Medicine Development mission

We transform innovative molecules
into medicines that change lives



Understanding Trial Design using Visualization

... from readout of phase 2 data to final phase 3 design



Visualizing trial design

The Challenge

- A checklist
- Time perspective – ready for the protocol and tool development
- Operational and scientific aspects
- Not a new tool

The Benefits

- A reminder of activities and time constraints
- Simplify protocol development
- Cross functional communication

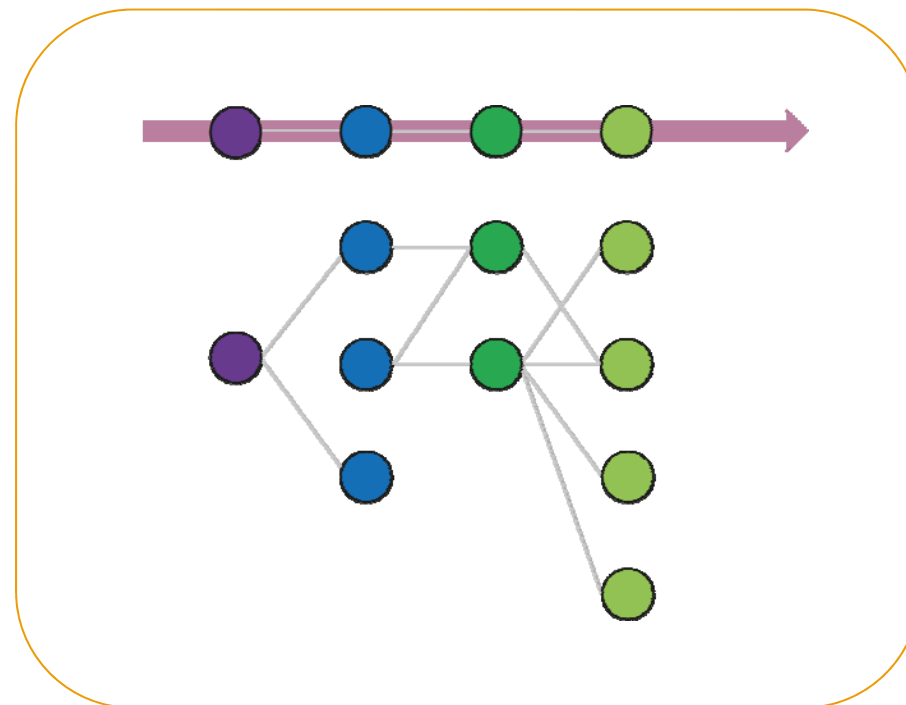


The result – an interactive guide

The checklist

- Describes design activities - mix of regulatory, operational and scientific perspectives
- Put time in focus when to be ready
- End of design and ready for protocol development

An introduction, a gentle reminder, or just a visualization guide of trial design!



Information sources



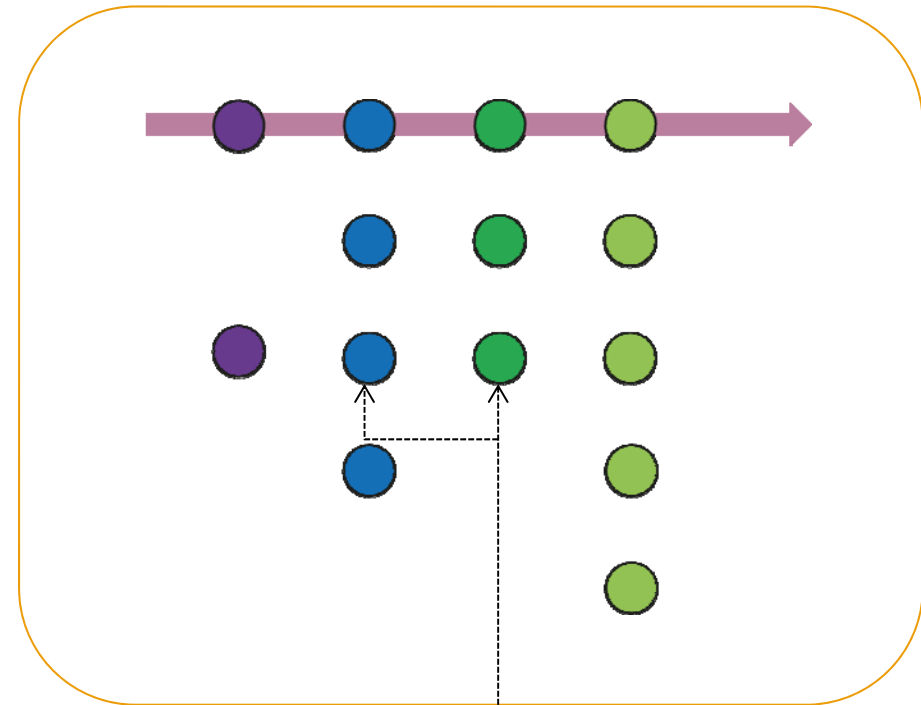
Governance interaction



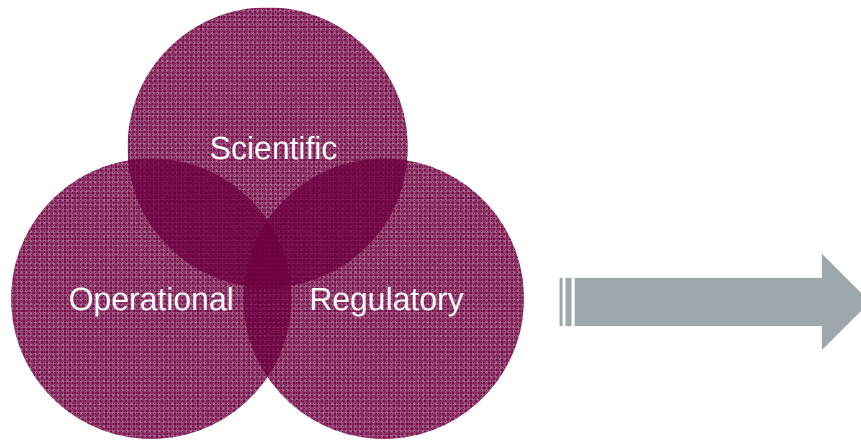
When to start and
be completed



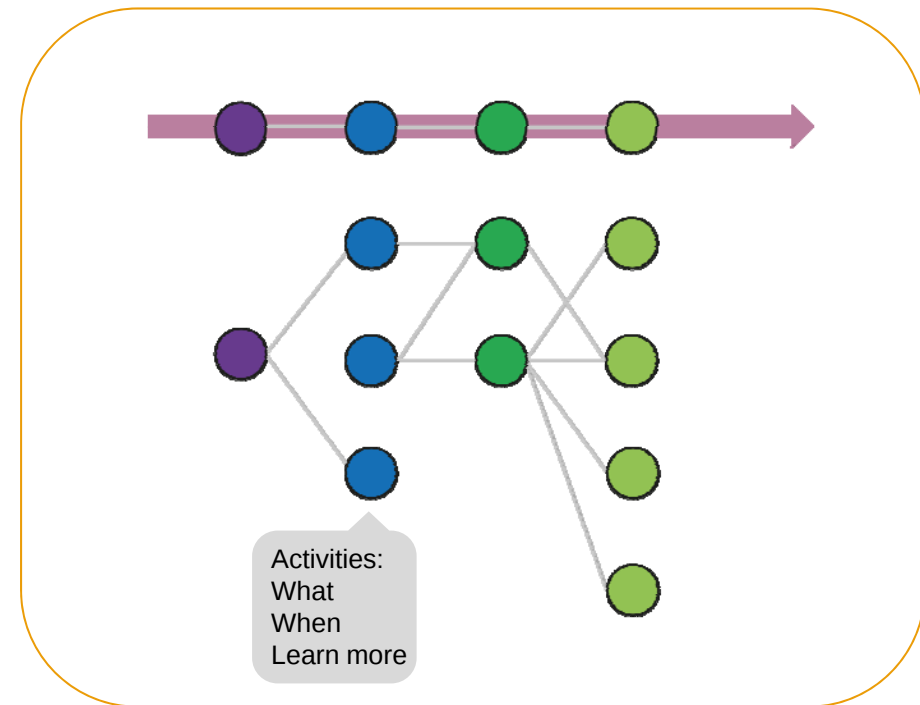
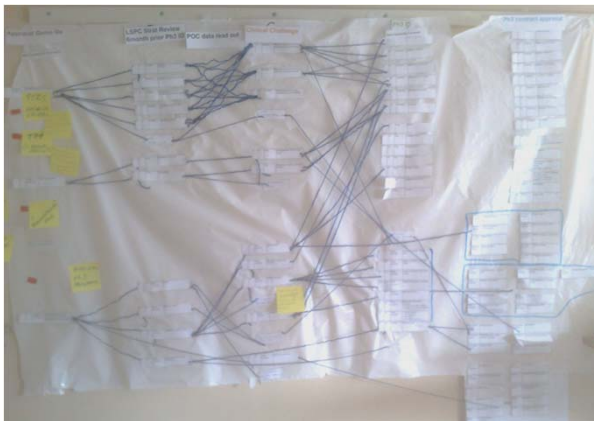
Headline turned
into activities



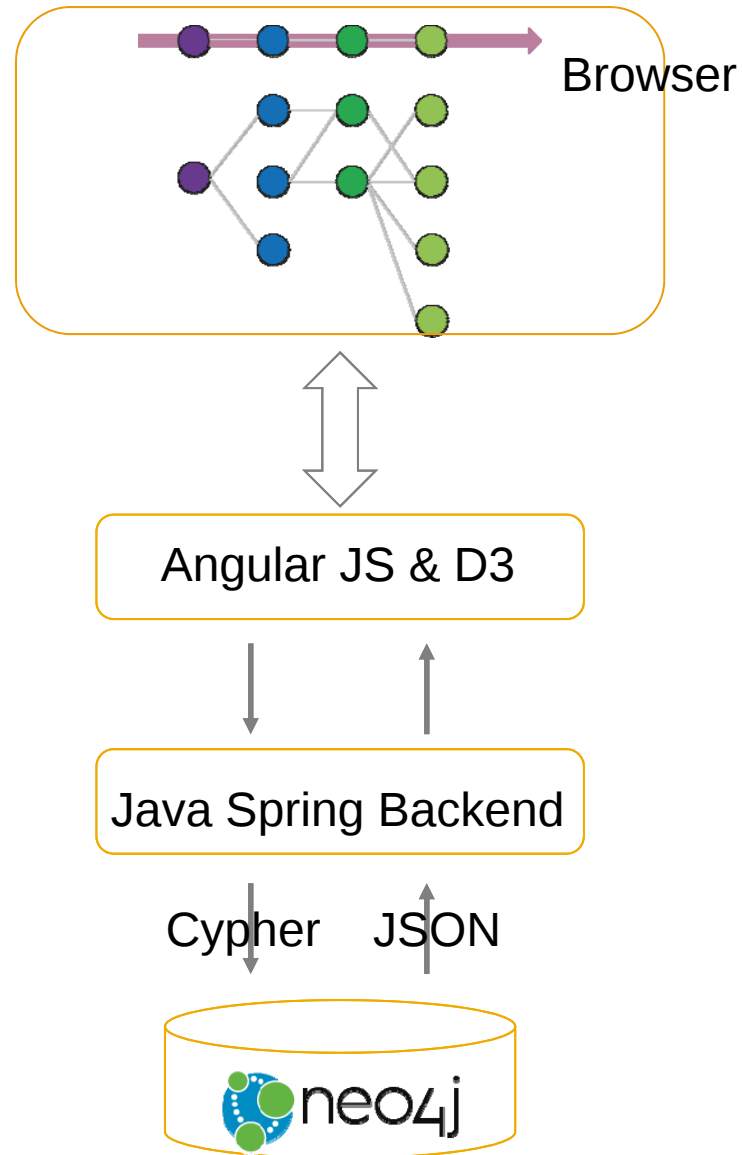
Organizing and relating information



All perspectives matters



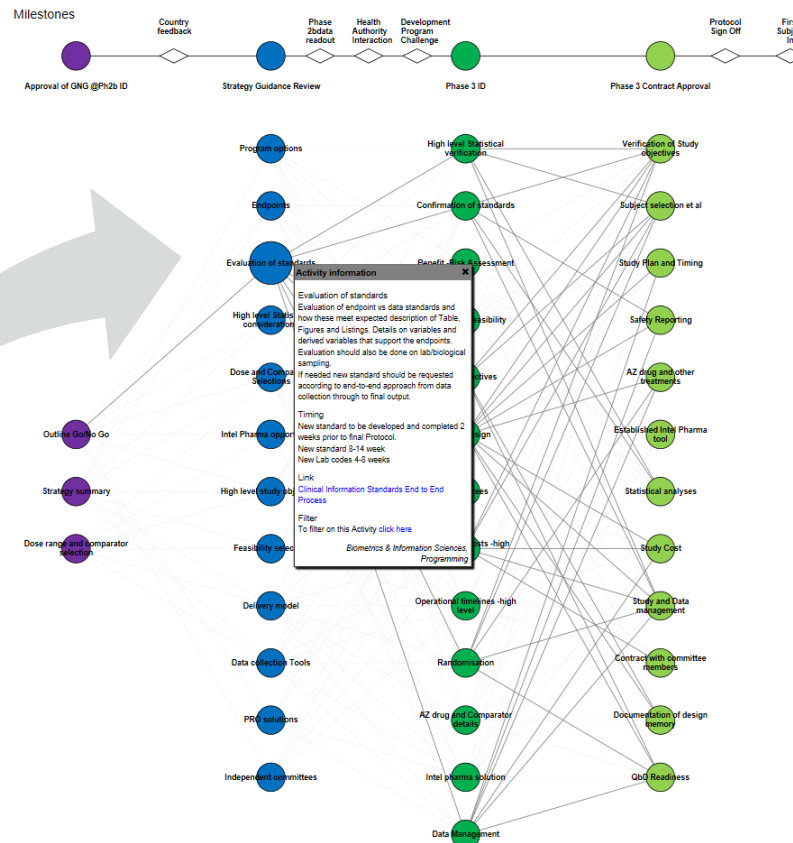
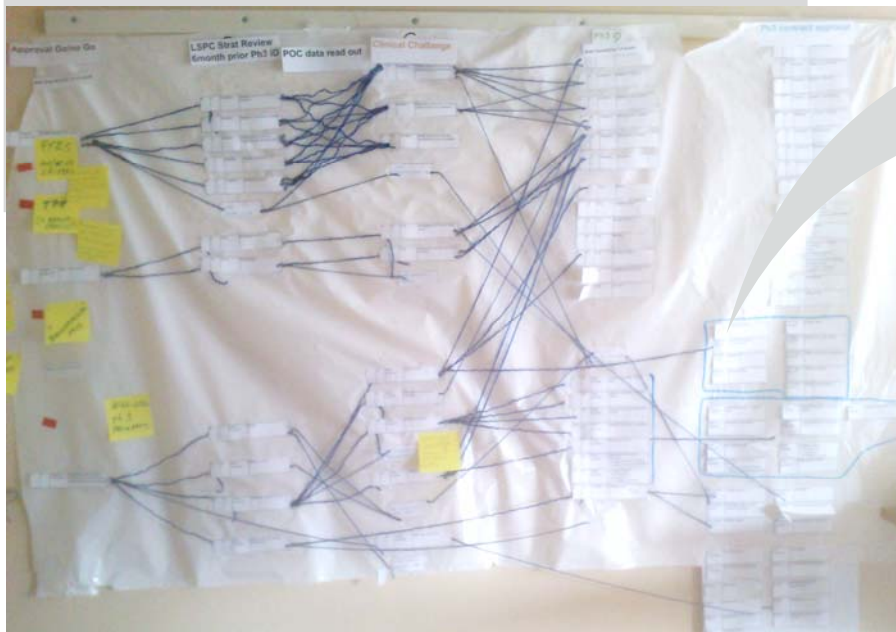
Technology solution of visualization



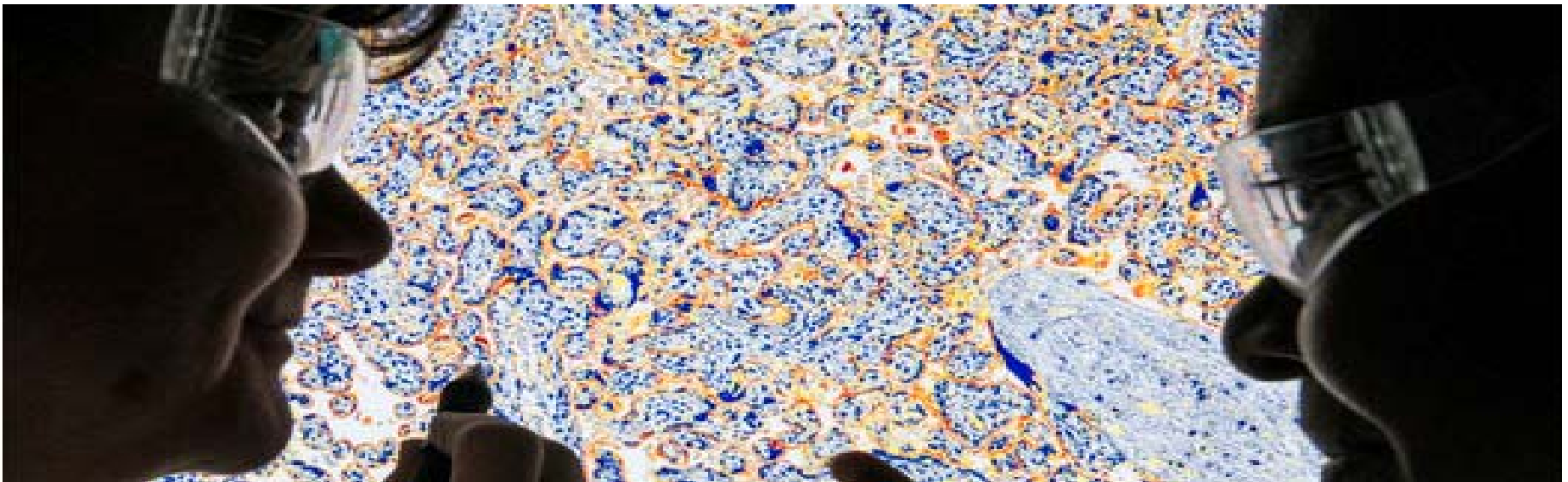
Summary: Visualization Trial Design

- Mix of perspectives important for design
- Time perspective – when to start or be ready
- A visualization of the design work to be ready for protocol development

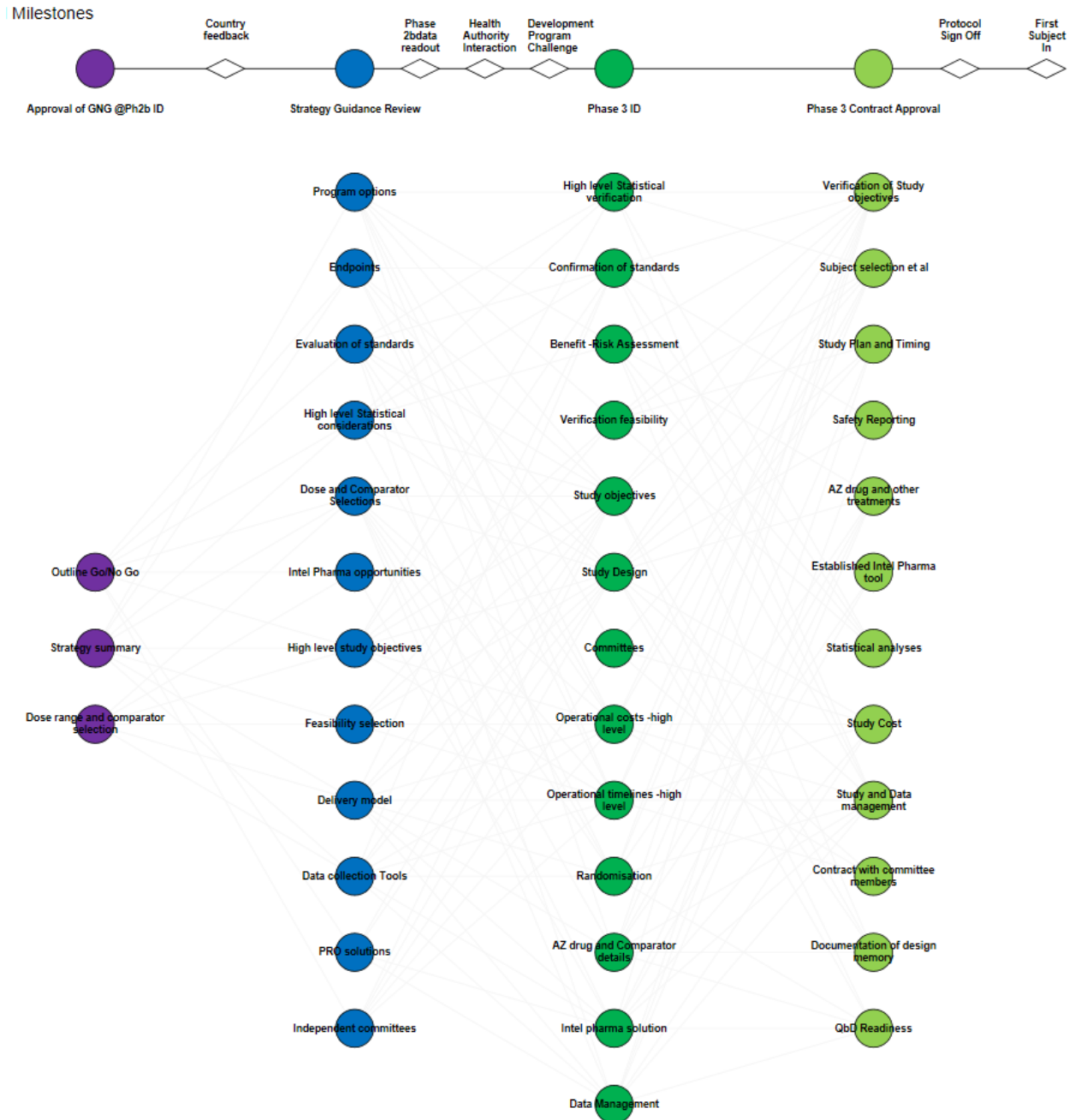
An introduction, a gentle reminder, or just a visualization guide of trial design!



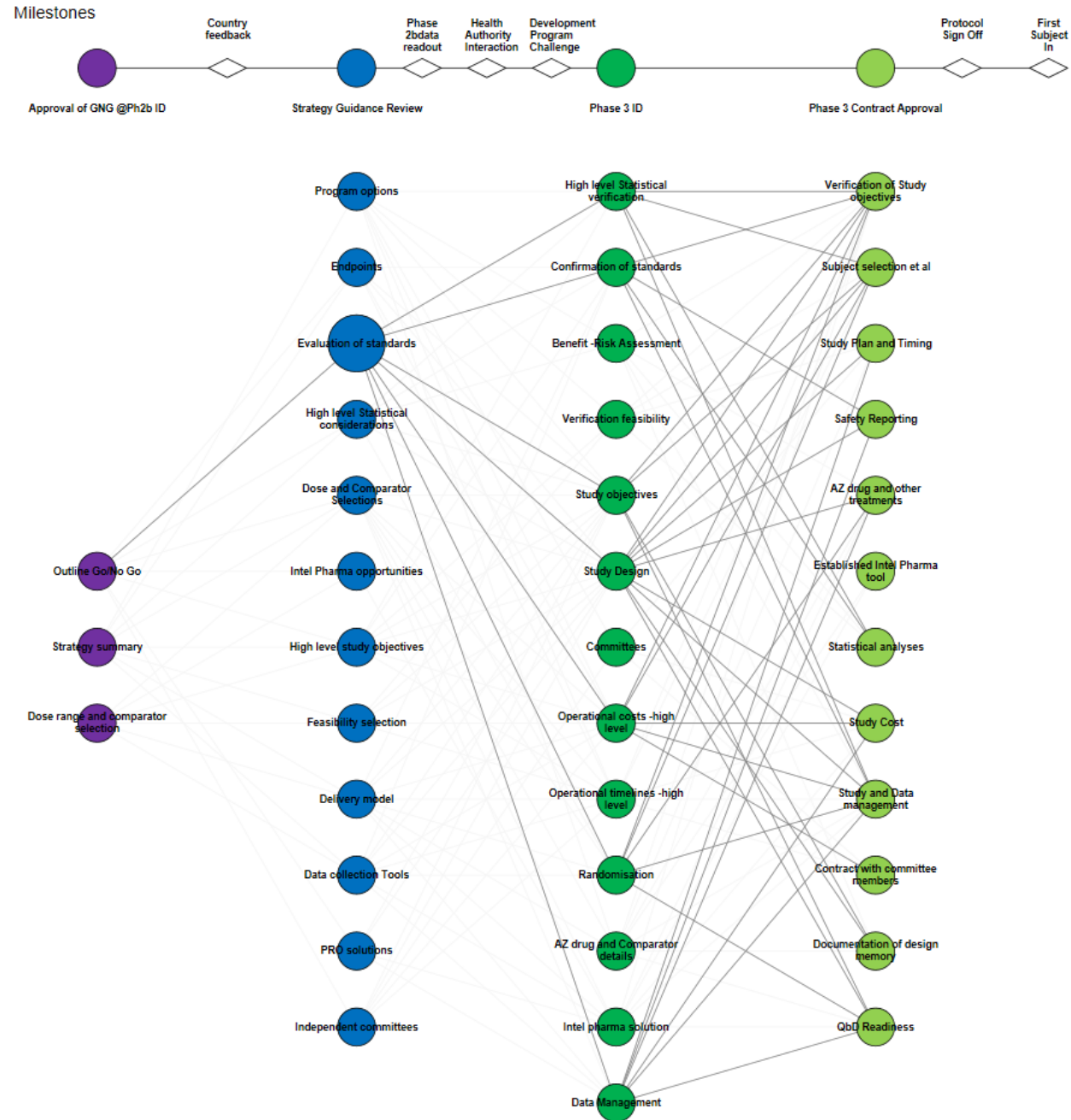
Demo



Demo Overview



Demo Relations



Demo Activity details

Evaluation of standards

Activity information 

Evaluation of standards
Evaluation of endpoint vs data standards and how these meet expected description of Table, Figures and Listings. Details on variables and derived variables that support the endpoints. Evaluation should also be done on lab/biological sampling.
If needed new standard should be requested according to end-to-end approach from data collection through to final output.

Timing
New standard to be developed and completed 2 weeks prior to final Protocol.
New standard 8-14 week
New Lab codes 4-8 weeks

Link
[Clinical Information Standards End to End Process](#)

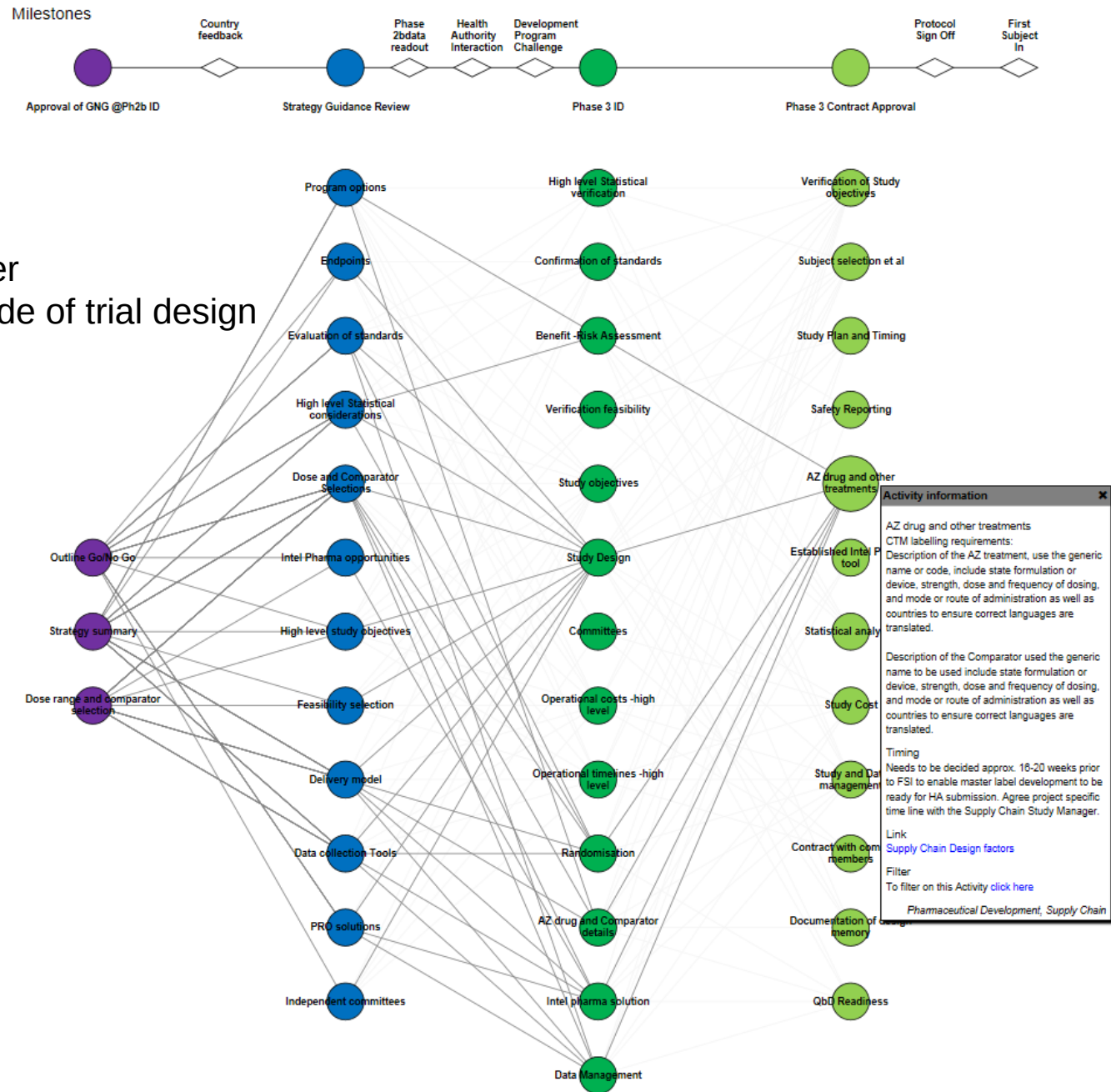
Filter
To filter on this Activity [click here](#)

*Biometrics & Information Sciences,
Programming*



Demo overview

- An introduction
- A gentle reminder
- Visualization guide of trial design



Understanding Trial Design using Visualization

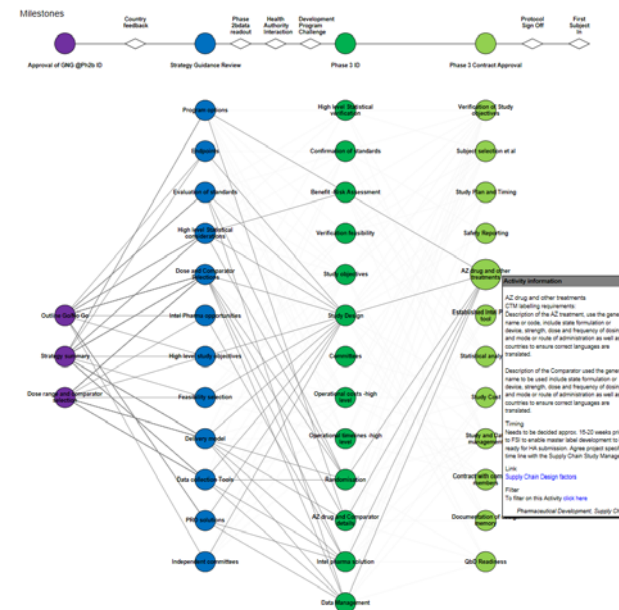
The Challenge

- A checklist
- Time perspective – ready for the protocol and tool development
- Operational, scientific and regulatory aspects
- Not a new tool

The Benefits

- A reminder of activities and time constraints
- Simplify protocol development
- A cross functional communication

The Future





Acknowledgement

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Key sponsors and enablers have been Martin Simán, Sarah Barber, Casten von Otter, Elisabeth Bolling-Sternevald.

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BACK Ups technology solution



Visualization architecture

