

DS03 – *The Digital Protocol is just the beginning. Or is it?*

Bill Qubeck and Thierry Philippe



OUR SPEAKERS TODAY



Bill Qubeck



Thierry Philippe



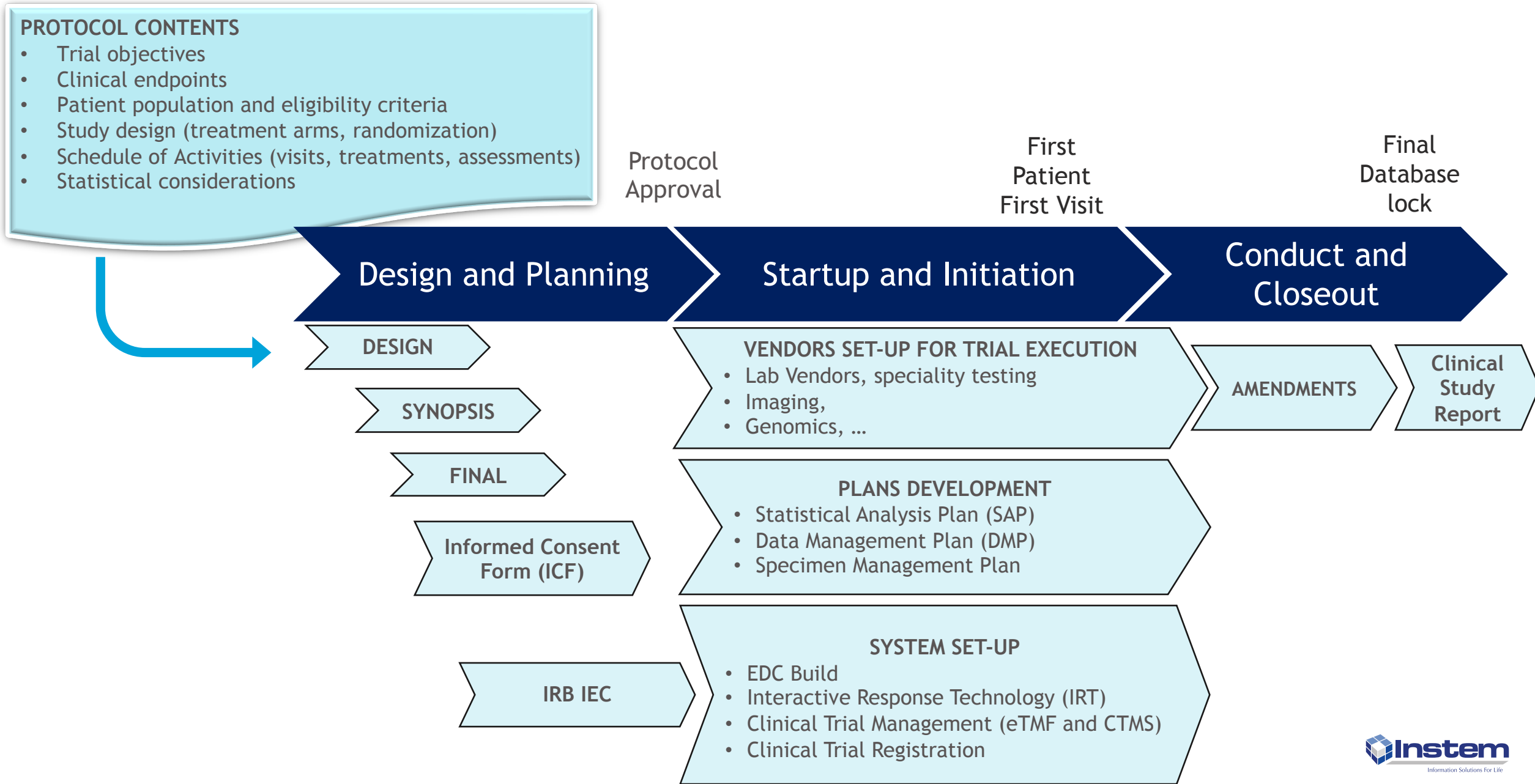


AGENDA

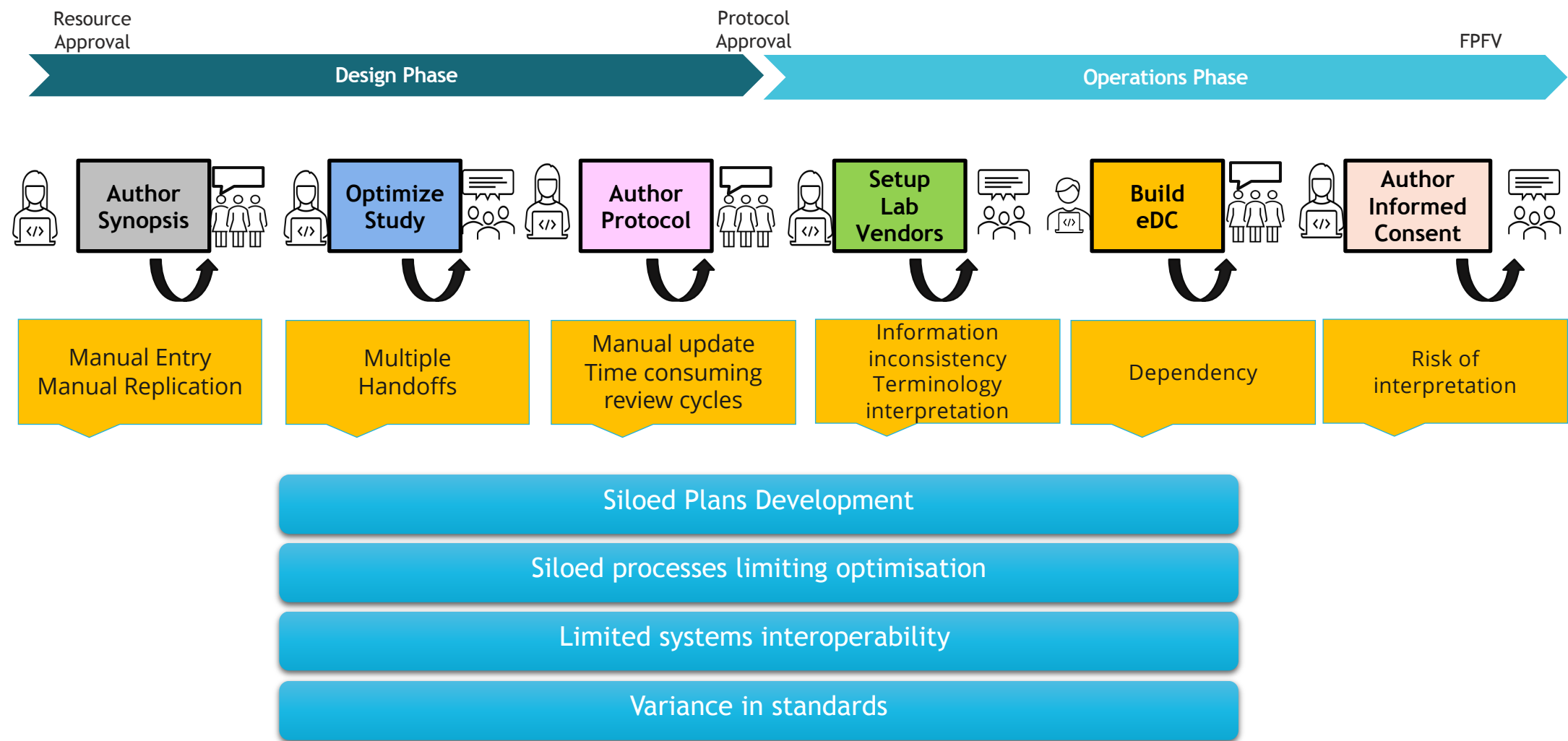
- Basics: What is a protocol and what are the challenges
- Digital protocol and end user experience
- Tackling a digital protocol project
- Wrap up

Protocol & Challenges

Clinical Trials from Protocol Perspective



Challenges





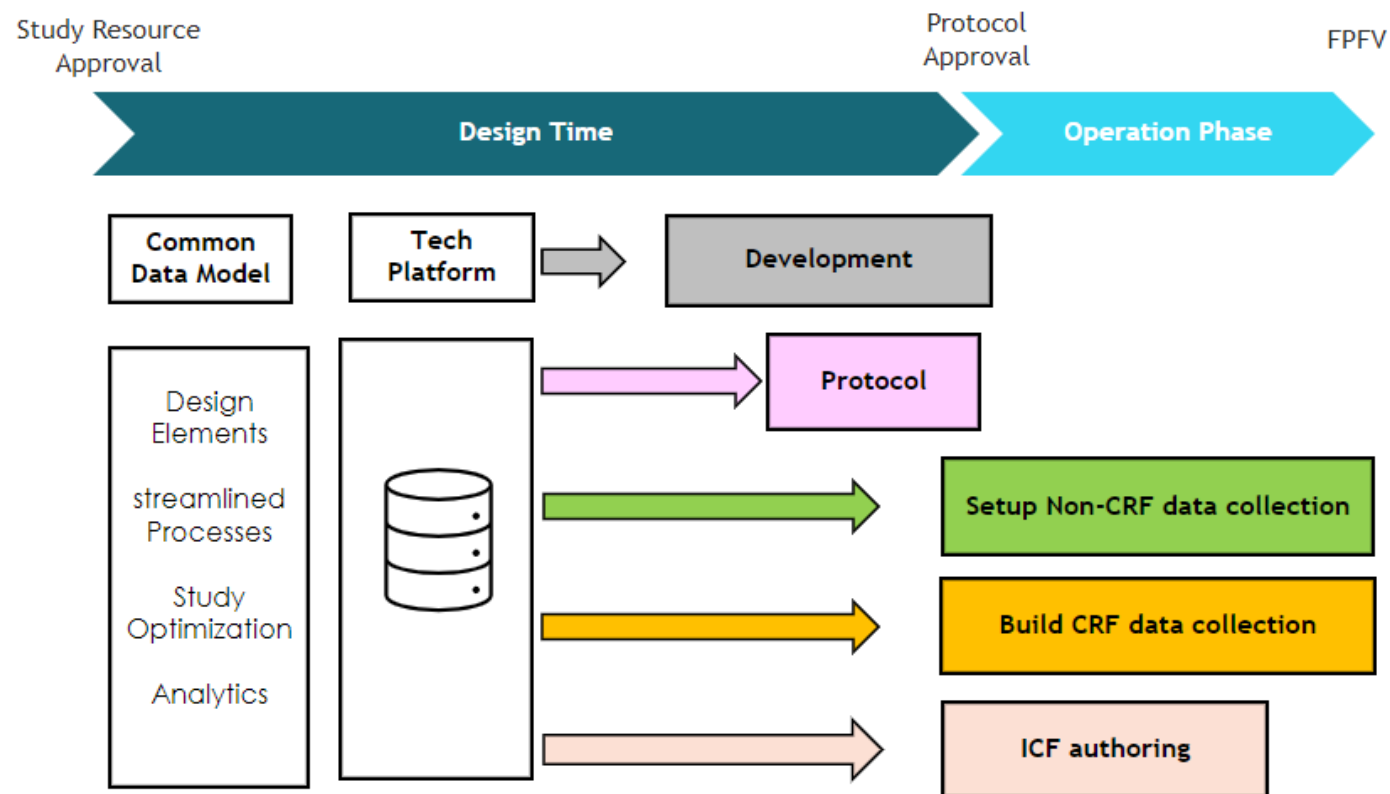
Digital Protocols and benefits

Single source of
design truth

Executable study
concept model

automated clinical
operations processes

Digital Protocol Approach



Streamlined customer experience



It is easier for me to incorporate insights into proposed study designs because I receive them earlier in the process.



I can begin downstream startup sooner based on a structured design concept and accelerate data collection operations (EDC build).



I save time writing and editing the protocol because I can rapidly generate portions of it in a consistent and high-quality manner.



Single source of truth



Common standards



Automation of operations



E2E Connectivity across functions



Design aids and tools



Development Team

I'm able to create planned visit schedules when the structured design concept is stabilized earlier.



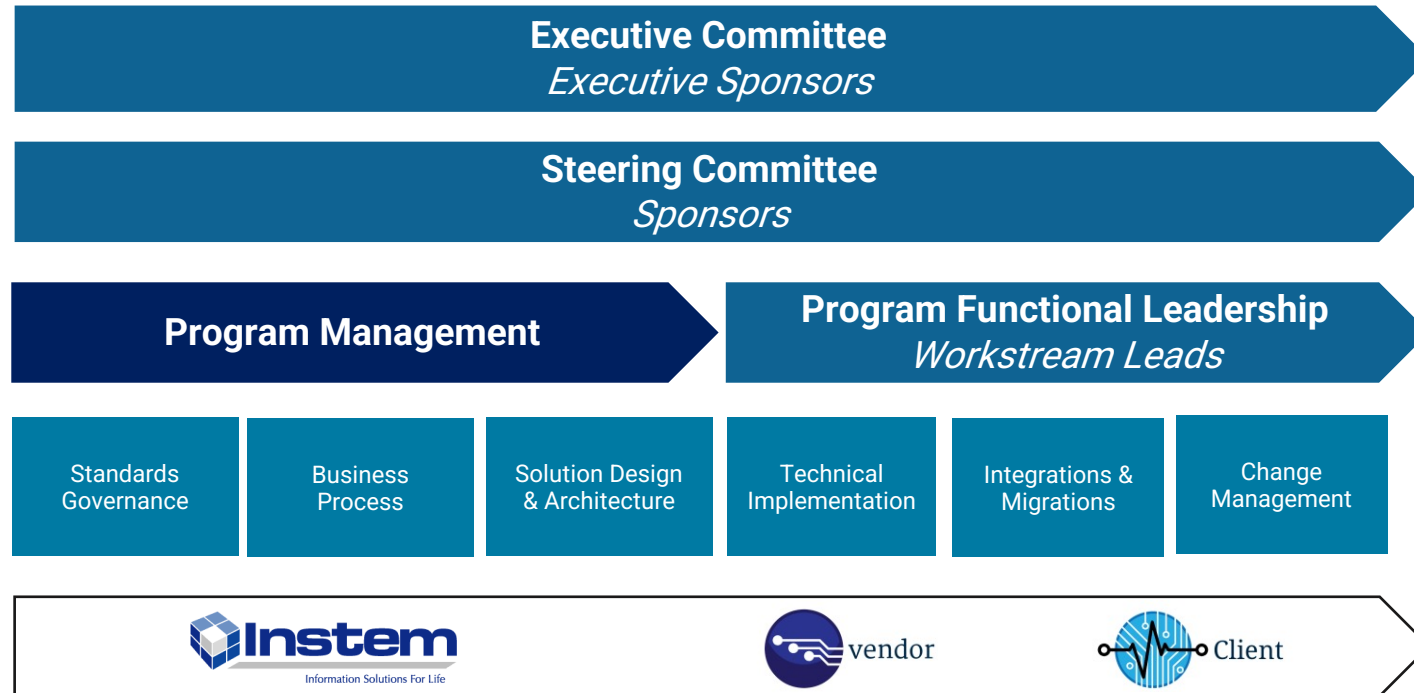
Outsourcing Managers

I can manage vendors more effectively using cost analysis based on the reports generated.

The background is a complex, abstract network of thin, light blue lines radiating from a central point, creating a starburst or web-like effect. Interspersed among these lines are numerous translucent, multi-colored spheres in shades of blue, green, and purple. These spheres have a glass-like texture with internal reflections and refractions, giving them a three-dimensional appearance. The overall color palette is cool, dominated by various tones of blue.

Tackling a Digital Protocols Project

Governance



Key Responsibilities

Executive Committee

- Provide strategic direction & intent

Steering Committee

- Oversight and guidance to DPS working teams

Program Management Office

- Manage overall project direction & execution
- Ensure alignment with Steering Committee & workstream leads

Program Functional Leadership

- Manage and deliver; promote adoption

Workstreams

- Each workstream will have delivery leads supported by business & technical resources
- Sub-teams within workstreams will be defined as necessary

Collaboration

- Provide partner support to drive workstreams and ensure program success through program governance

Key factors for Success



BUSINESS VALUE



USER ADOPTION



**DELIVERABLES
OPTIMISATION**



**FUTURE READY
ARCHITECTURE**



**TESTING AND
VALIDATION**

Digital Protocol Project Workstreams

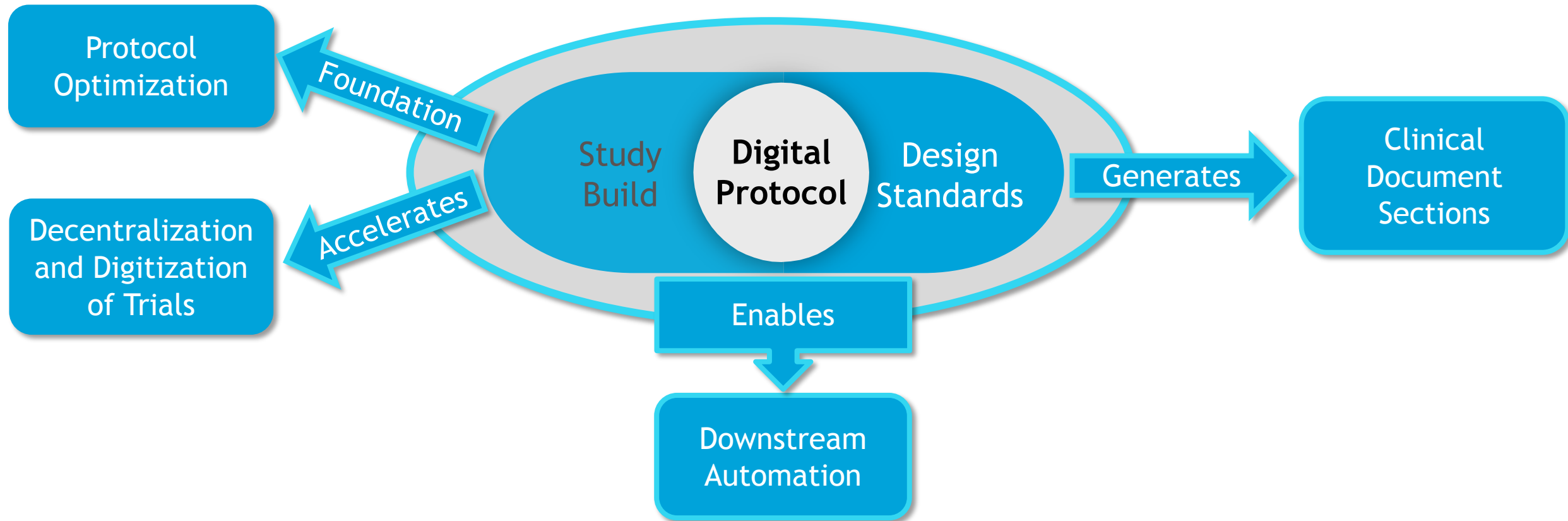
R = Responsible
A = Accountable
S = Supporting
I = Informed

Workstreams		Description
1	Program Management	• Manages overall project management, cross-workstream orchestration, and day to day project delivery • Program structuring, timelines, and financials
2	Standards: Digital Protocol Foundations	• Digital protocol foundations will define, reconcile, and coordinate the protocol foundation definitions across R&D functions • Workstream will develop a strategy to incorporate defined protocol foundation elements and establish the roadmap for capabilities
3	Database Build	• Lay the core technical foundation for EDC build • Generate initial EDC build or database spec • Align on future state integration/implementation • Pilot capabilities as they become available and provide learnings
4	Protocol Optimizations	• Integration • Deliver activities related to data management, protocol optimization
5	Change Management	• Facilitate organizational change management • Change management strategy, aligned to business implementation



Wrap up

Revolutionize protocol design and empower the automation of subsequent startup procedures



A surreal landscape featuring a stone path of circular stepping stones leading from the foreground into a body of water. In the middle of the water, there is a circular platform with a small pavilion structure. The pavilion has four pillars and a roof covered in dense, purple, vine-like foliage. A wooden bench is placed inside the pavilion. In the background, there are rolling hills or mountains under a soft, purple and pink sky, suggesting a sunset or sunrise. The water reflects the colors of the sky and the structure.

“A journey of a thousand miles
must begin with a single step” –
Lao Tzu





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and life-enhancing science.