Designing Trials to Reduce Patient and Site Burden

Jenny Higley, Director, Feasibility Center of Excellence
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Designing Trials to Reduce Patient and Site Burden

How to create a patient-centric clinical protocol to obtain the necessary data and validate your primary objective

The importance of developing/applying tools and managing different stakeholders to pressure test our plans to have less complicated protocols

The importance of creating a collaborative relationship with sites during protocol development targeting reducing patient burden

Kyle, living with Friederich’s ataxia

What does it mean to create a patient-centric protocol?

Designing a study that **prioritizes the well-being and convenience of the patients** while ensuring the collection of accurate and relevant data to validate the primary objective

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Patient-Centric Approach to Protocol Design

Biogen is in the process of implementing new capabilities to enable protocol simplification and reduce patient burden

- Developing protocols from with authoring tools that enable measurement of complexity and patient burden from initial draft
- Pressure testing draft protocols throughout the study design and planning process

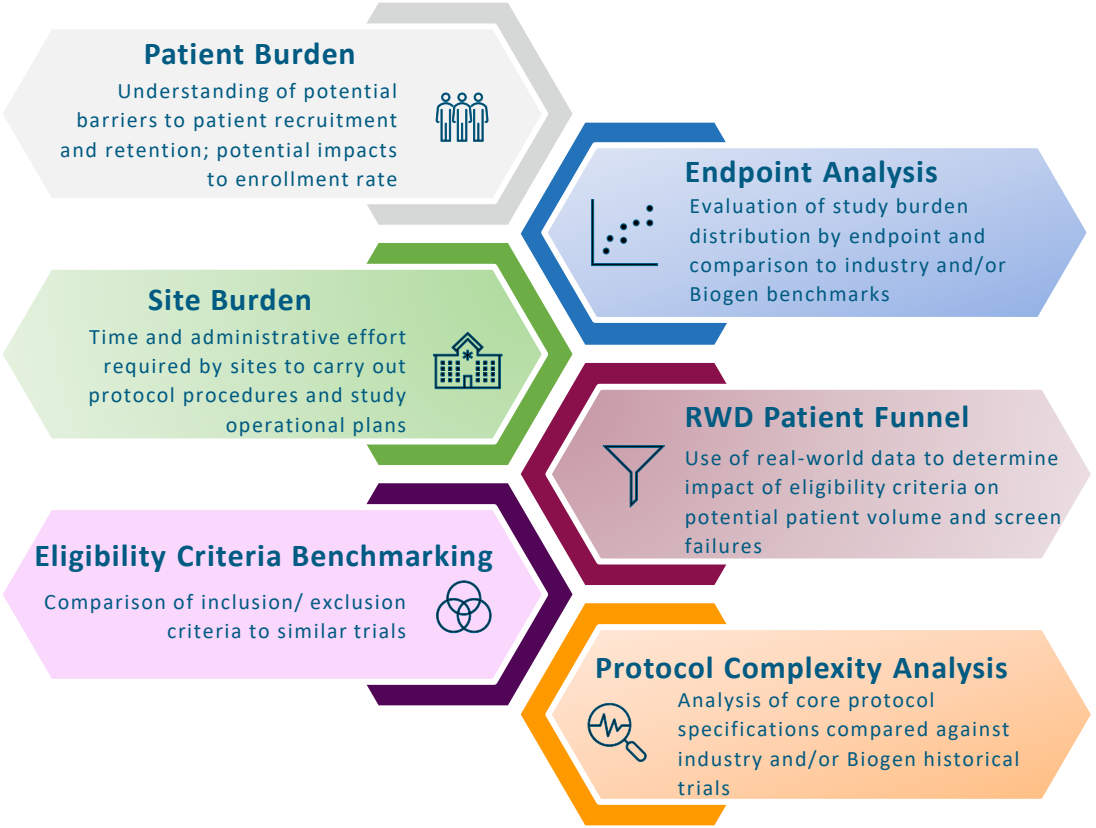
7 of 13 Feasibility groups that are part of the ZS Consortium are now doing protocol analytics in addition to ‘traditional’ feasibility work

All of the Feasibility groups doing protocol analytics are using their own **in-house designed systems and tools**

Pressure Testing Protocols to Reduce Complexity

Protocol Feasibility Analysis

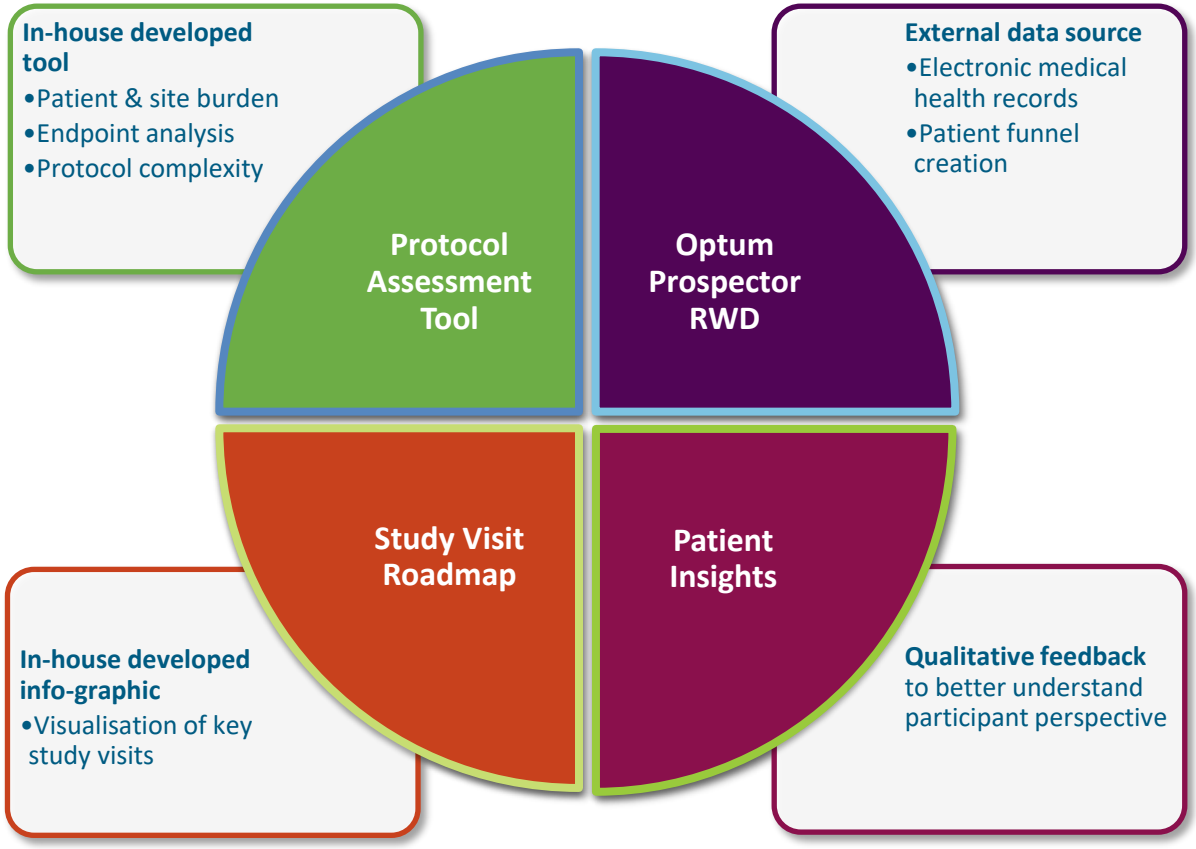
Each protocol is evaluated using a combination of a Biogen-developed "Protocol Assessment Tool," benchmarking of similar studies, patient insights published industry protocol complexity metrics.



Protocol Feasibility Assessment Output

A comprehensive report details the 8 core PFA components

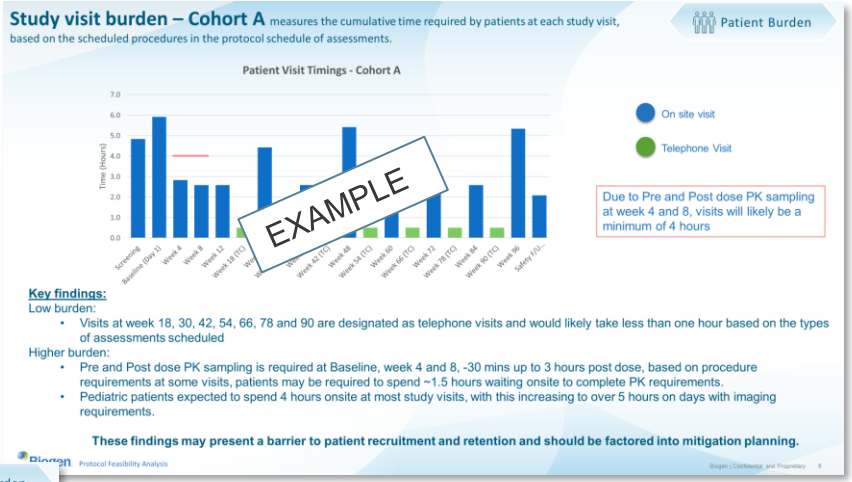
Tools, technology, and data sources

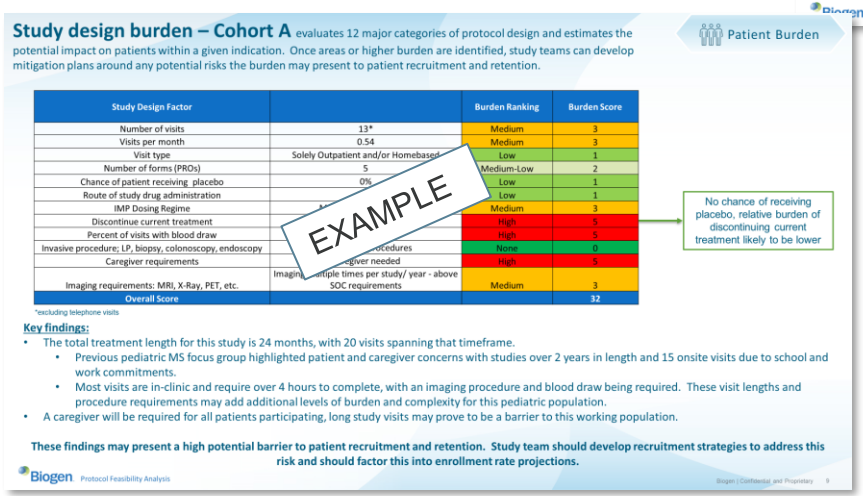


Patient burden analysis

Evaluates 3 key areas:

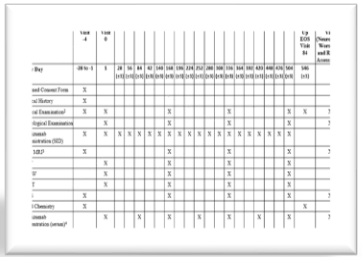
- Study visit burden
- Study design burden
- Insights from patients



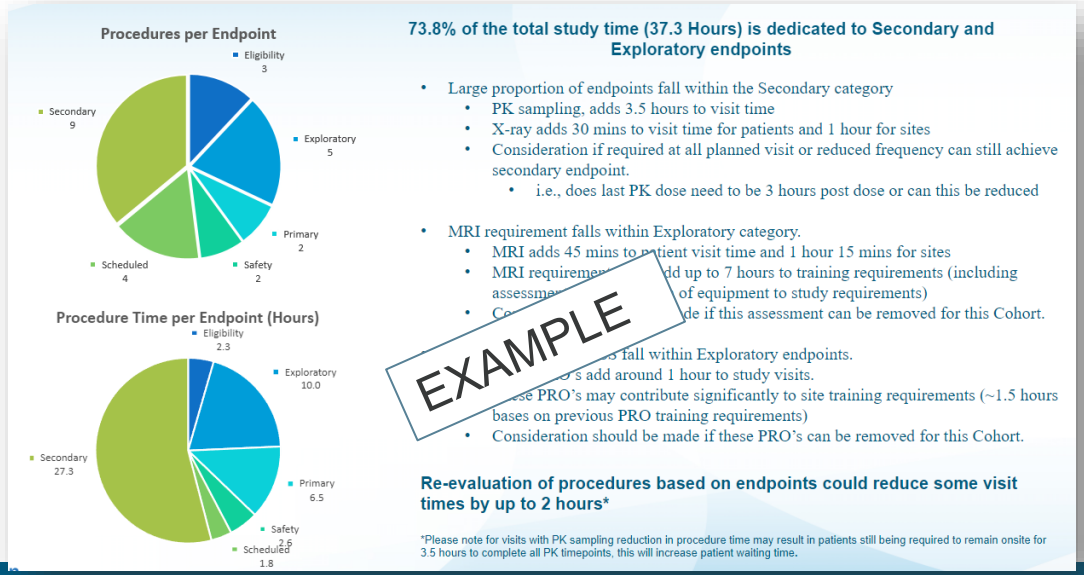


- "Is it possible to decrease burden on patients and sites?"
- "Is there an opportunity to reduce visit frequency?"
- "Can we reduce lengthy/ burdensome procedures?"
- "Can we mitigate burden through recruitment and retention strategies?"

Endpoint analysis



- Distribution of procedures per endpoint type
- Proportion of study time by endpoint type



- Is there a relatively high number of exploratory endpoints?
- Is a large amount of time spent on exploratory endpoints?
- Can activities and procedures be re-evaluated to focus more on primary endpoints?

Collaboration with Sites in Study Design

Site burden analysis

Evaluates 3 key areas:

- Site training requirements
- Study visit burden
- Study design burden

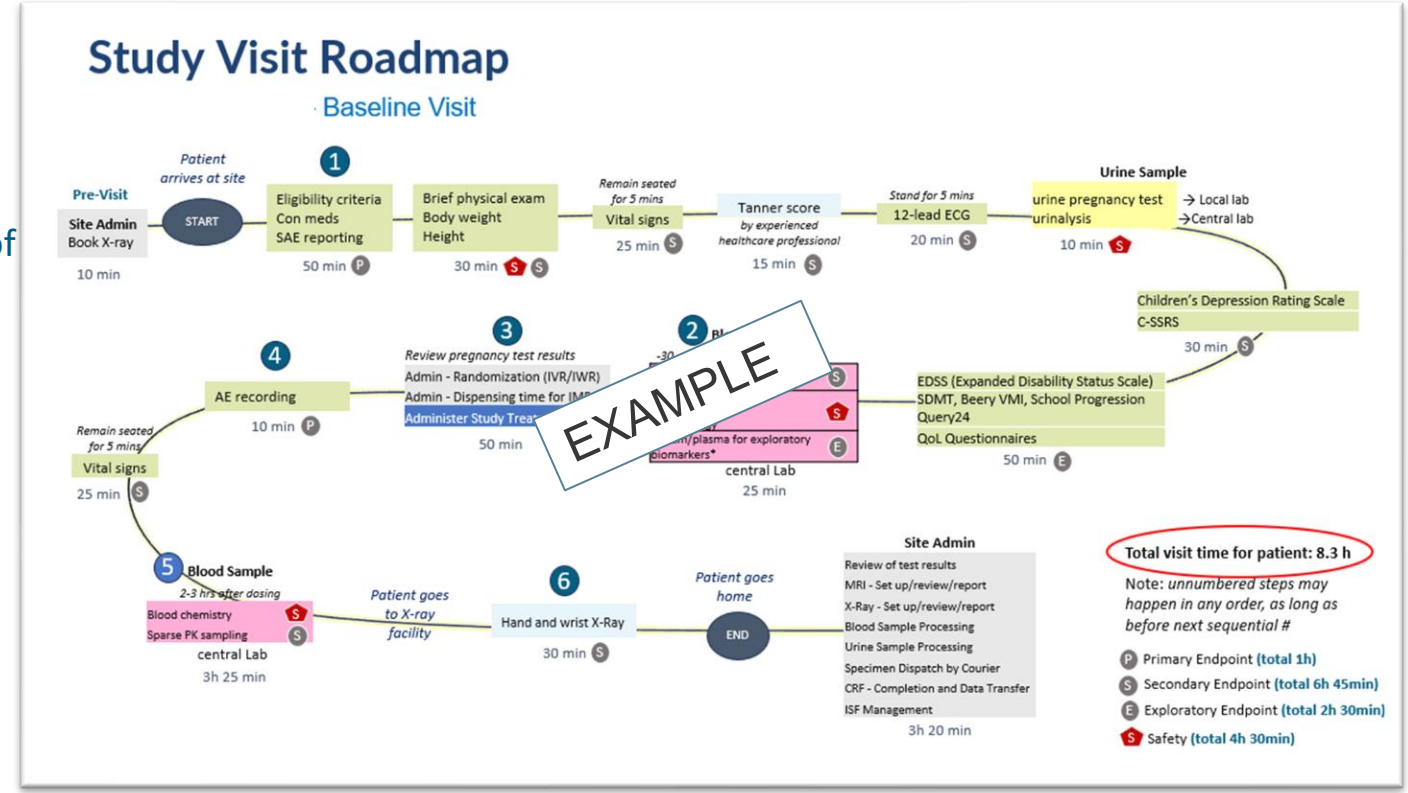
"Are there ways we can decrease burden on sites?"

"Can we reduce training requirements for sites?"

"Does the protocol design require a large number of vendors?

Study visit roadmap

- Step-by-step visualization of burden per visit:
  - Patient
  - Site
  - Study design
- Developed for key study visits





For additional information or questions contact:
jenny.higley@biogen.com