Clinical Development for the Digital Age
The Clinical Protocol is the Core of Clinical Development
Traditional Study Design

Clinical trial complexity has increased
- Average number of procedures has doubled since 2005
- Average of 10,000 documents in a clinical trial

Amendments (fixing)
- (78%) phase II protocols have 2.7 substantial amendments
- 69% of phase III protocols have at least one substantial protocol amendment
- Average 2.7 and 3.3 per protocol respectively
- Average $500k per amendment

Key decisions and learnings are lost in resolved redlines in flat text (Word). We don’t learn.

Source: Tufts Center for the Study of Drug Development
How do we solve these protocol design issues within pharma?
Faro’s cloud platform addresses the operational problems and delays caused by the traditional word processing and spreadsheet driven method of clinical protocol development.

**Faro Smart Designer**

1. **User-friendly**
   - Software assisted design of the SoA powered by standards and metadata.

2. **Intuitive**
   - Optimization algorithms provide recommendations for modern DCT approaches.

3. **Collaborative**
   - A single software platform connecting all stakeholders in the clinical trial ecosystem providing real-time insights as design decisions are made.

4. **Efficient**
   - Operational efficiency of protocol implementation with a patient-centric focus.
<table>
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<tr>
<th>Feature</th>
<th>Description</th>
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<tr>
<td><strong>Faro Smart Designer</strong></td>
<td>SaaS platform that eliminates manual process and leverages technology to assist with lean protocol design and authoring.</td>
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<td><strong>Ideas &amp; RWD</strong></td>
<td>Combine study concepts and RWD to see the reality of patient impact.</td>
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<td><strong>Less is More</strong></td>
<td>Helps teams to balance scientific complexity.</td>
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<td><strong>Operational Reality</strong></td>
<td>Analyze trial designs for operational feasibility.</td>
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<td><strong>Flexibility is Critical</strong></td>
<td>Allows design teams to work without rigidity in process while maintaining structure.</td>
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<td><strong>Idea to Reality</strong></td>
<td>Push trial designs into workable documents.</td>
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<td><strong>Digital Data Flow</strong></td>
<td>Prepare for downstream systems integrations with an accurate single source of truth.</td>
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<td><strong>Built by designers for designers</strong></td>
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Optimize Study Designs With Real Word Data

Compare two different design scenarios with a click

Study activity costs with Liver biopsy

Study activity costs without Liver biopsy
Patient Journey

Teams can use real world data to view the study from different perspectives
Site Perspective

Teams can use real world data to view the study from different perspectives.
Immediate and Long-Term Benefits

Built on Microsoft Azure, the Faro platform allows real-time intel to transform potential benefits across a multitude of variables.

- Trials can start faster.
- Cost savings from earlier trial start, improved attrition among other things.
- Decrease in complexity of design.
- Time reduction for design phase to full protocol.
- Pt. recruitment & attrition rate improvements.
- Fewer amendments required.
Thank you

Together, we can improve lives by simplifying clinical research.

Questions?
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