TransCelerate
BIOPHARMA INC.

ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

Pre-Competitive Collaboration in Clinical Trial Execution

October 2012

Member Representation for TransCelerate BioPharma, Inc.

John Leonard (Board Member)
SVP Global Pharmaceutical R&D
David Jordan (Operations Committee)
Divisional VP, Stats & Data Mgmt

Anders Ekblom (Board Member)
Head of Science & Technology
Sue McHale (Operations Committee)
Executive Director, Global Project Delivery

Brian Daniels (Board Member)
SVP Global Development & Medical Affairs
Jonathan Zung (Operations Committee)
Vice President, Global Development Operations

Lynn Marks (Board Member)
SVP, Medicines Development Centre for Infectious Disease
Pete Milligan (Operations Committee)
Director, Lead for SCD

Paul Stoffels (Board Member)
Worldwide Chairman, Pharmaceuticals Group
Martin Fitchet (Operations Committee)
SVP Projects, Clinical Platforms & Sciences

Jan Lundberg (Board Member)
EVP of Science and Technology
Jeff Kasher (Operations Committee)
VP and COO Global Medical R&D

Mikael Dolsten (Board Member)
President of Worldwide R&D
Craig Lipset (Operations Committee)
Head of Clinical Innovation

Corsee Sanders (Board Member)
Global Head of Development Innov. & Clin Ops
Jill Vath (Operations Committee)
Senior Director at Genentech
Ben Szilagyi (Operations Committee)
Global Head Clin Data & Info Science

Elias Zerhouni (Board Member)
President of Global R&D
Ji Zhang (Operations Committee)
Head of R&D Scientific Platforms
Andy Lee (Operations Committee)
SVP, Head Global Clin Ops, Genzyme

Klaus Dugi (Board Member)
Corporate SVP, Medicines
Thor Voigt (Operations Committee)
Head of Global Clin Ops, Biometrics & Data Mgmt

R&D Leadership identified clinical trial execution as a key priority area for industry-wide collaboration

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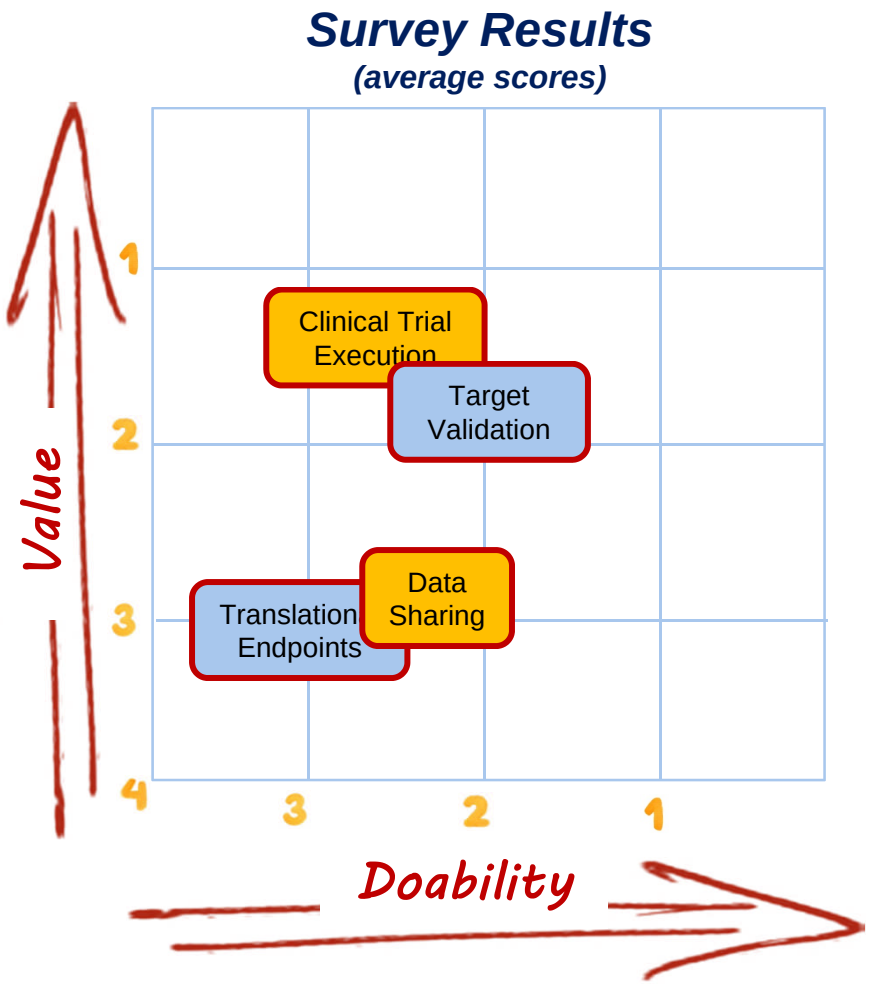


On Value…

"We need 30-50% cost reduction."

"Sharing of infrastructure is an opportunity."

"Clinical trials is by far most important. Challenges include regulation, globalization, complexity…definitely discuss ways of addressing the investigator cost."

"We have already implemented major changes in clinical operations, but we are interested in more "industrial" trial site execution."

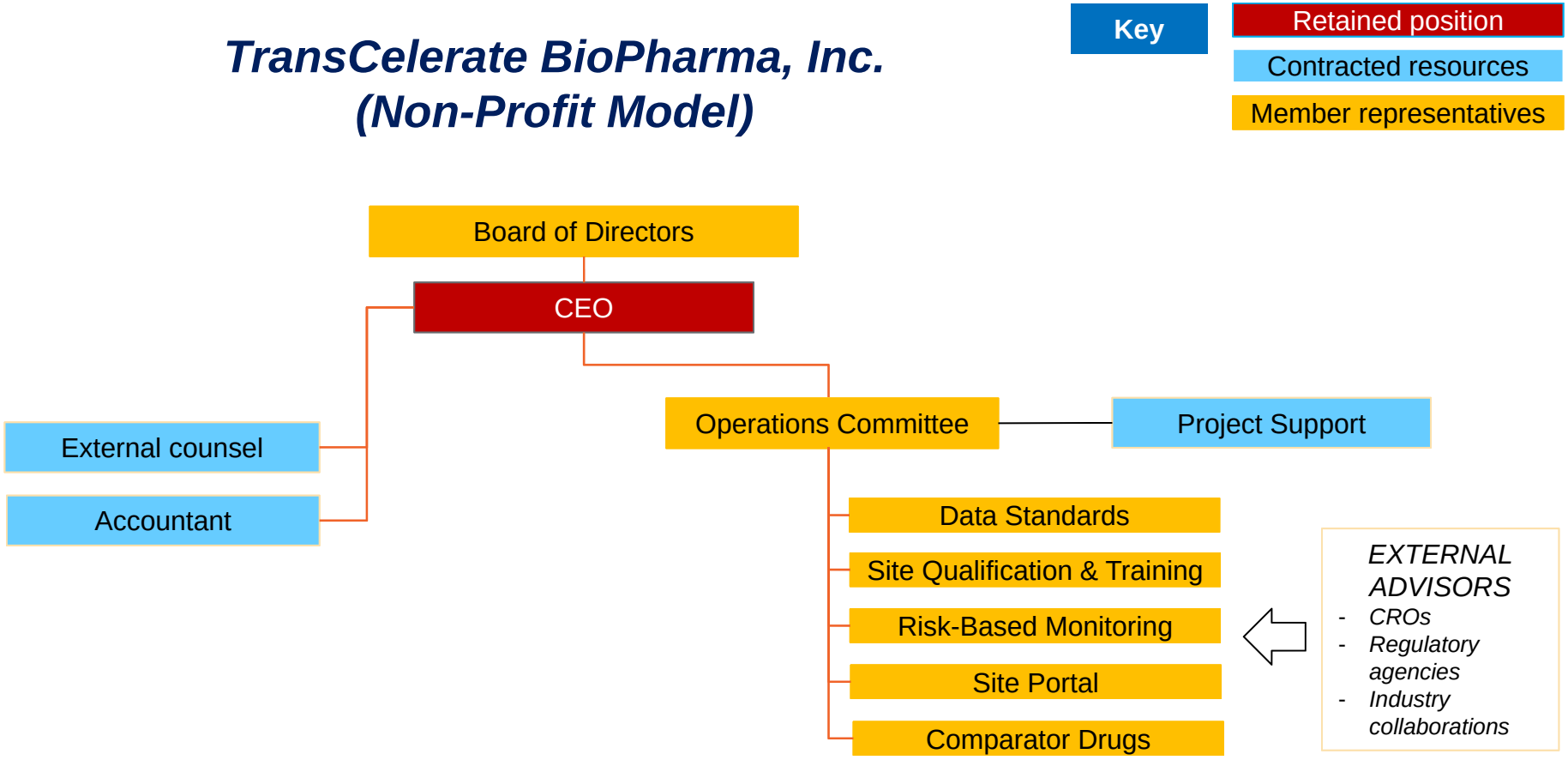
On Doability…

"Requires regulator endorsement."

"Sharing of infrastructure is a major opportunity."

TransCelerate BioPharma has been established to provide governance and dedicated execution support for project activities

A flat organization structure emphasizes a high level of membership participation. The organization provides governance and execution support for funded initiatives.



TransCelerate BioPharma Mission Statement

"TransCelerate BioPharma will develop shared industry research and development solutions to simplify and accelerate the delivery of innovative products to patients. Our non-profit, pro-competitive model will be based on a results-oriented approach, emphasizing increased quality in clinical trials and improved patient safety, enabled by broad participation and collaboration across the global research and development community."

TransCelerate BioPharma Inc. has passed some important milestones over the past few months, with more to come….

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So far this year…

- August 2012: TBI incorporated with10 charter members & held the inaugural Board of Directors meeting with R&D Heads
- September 2012: Press announcement was released

Pharmaceutical Companies Unite to Accelerate Development of New Medicines

PHILADELPHIA – SEPTEMBER 19, 2012 – Ten major pharmaceutical companies announced today that they have formed a non-profit organization to facilitate pre-competitive collaboration that accelerates development of new medicines. Abbott, Astra-Zeneca, Boehringer-Ingelheim, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Pfizer, Roche and Sanofi launched ***TransCelerate BioPharma***, the largest ever initiative of its kind…

- September / October 2012: Several new companies have approached TBI with an interest to join
  - Merck Serono, Onyx Pharmaceuticals, Biogen Idec

Five opportunities were prioritized based on the shared goals of quality, patient safety and accelerated development timelines

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ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

Prioritized Near Term Opportunities

After an extensive evaluation process, investment has been made to advance five collaboration projects.

1. **Standardized Approach for High-Quality, Risk-Based Monitoring**

[redacted]

2. [redacted]

3. [redacted]

4. **Clinical Data Standards – Efficacy** (*in partnership with CDISC*)

Objective: Accelerate current efforts underway through CDISC to establish efficacy data standards
Benefits: Increased quality of clinical data and enablement of industry end-to-end data flow

5. **Comparator Drugs for Clinical Trials** (*marketed drugs only*)

Objective: Establish a supply model to source comparator drugs between companies for use in trials
Benefits: Enhanced patient safety due to known product source and acceleration of study timelines

The project activities kicked off in June 2012 with full mobilization of the working teams; progress is underway

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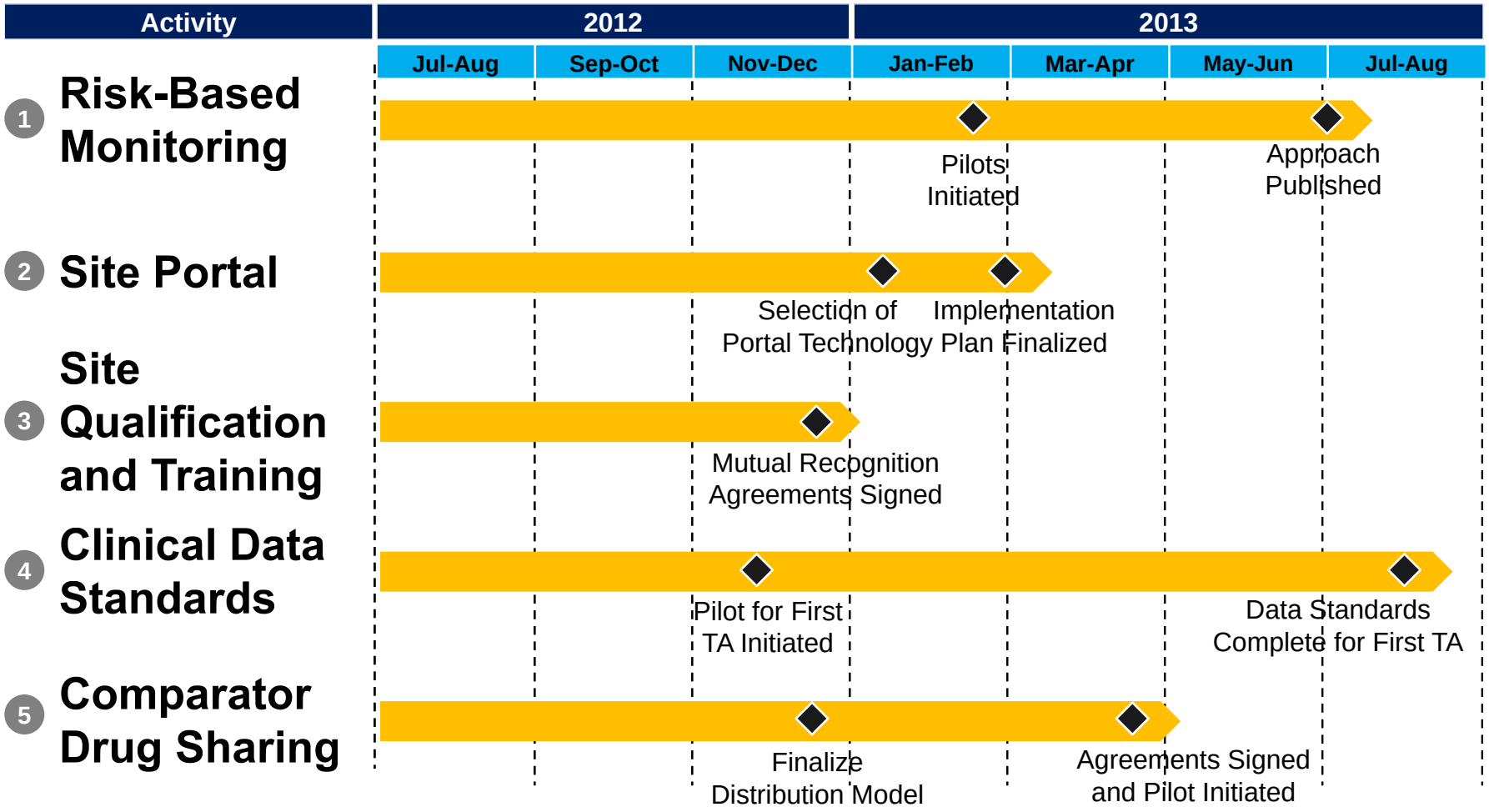

◆ Project-Level Milestone

The intent is not to recreate, but rather partner with existing collaborations which closely align with project activities

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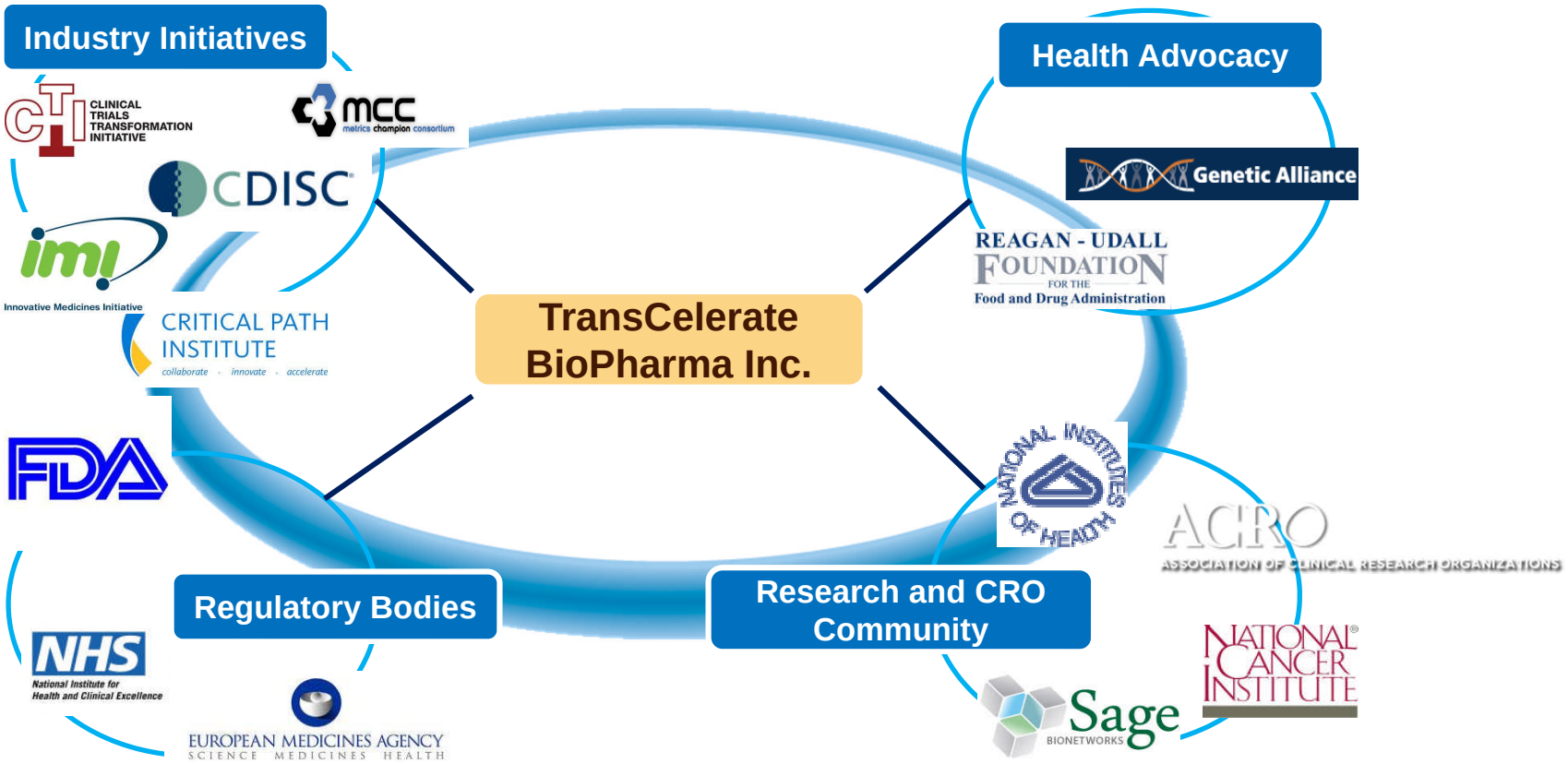
Engagement with the Larger Ecosystem

Outside organizations, including regulatory, public, government and industry-based entities, are being engaged.



Appendix: Project Summaries

Five opportunities in clinical trial execution were prioritized for action based on industry readiness and ability to execute in 2012

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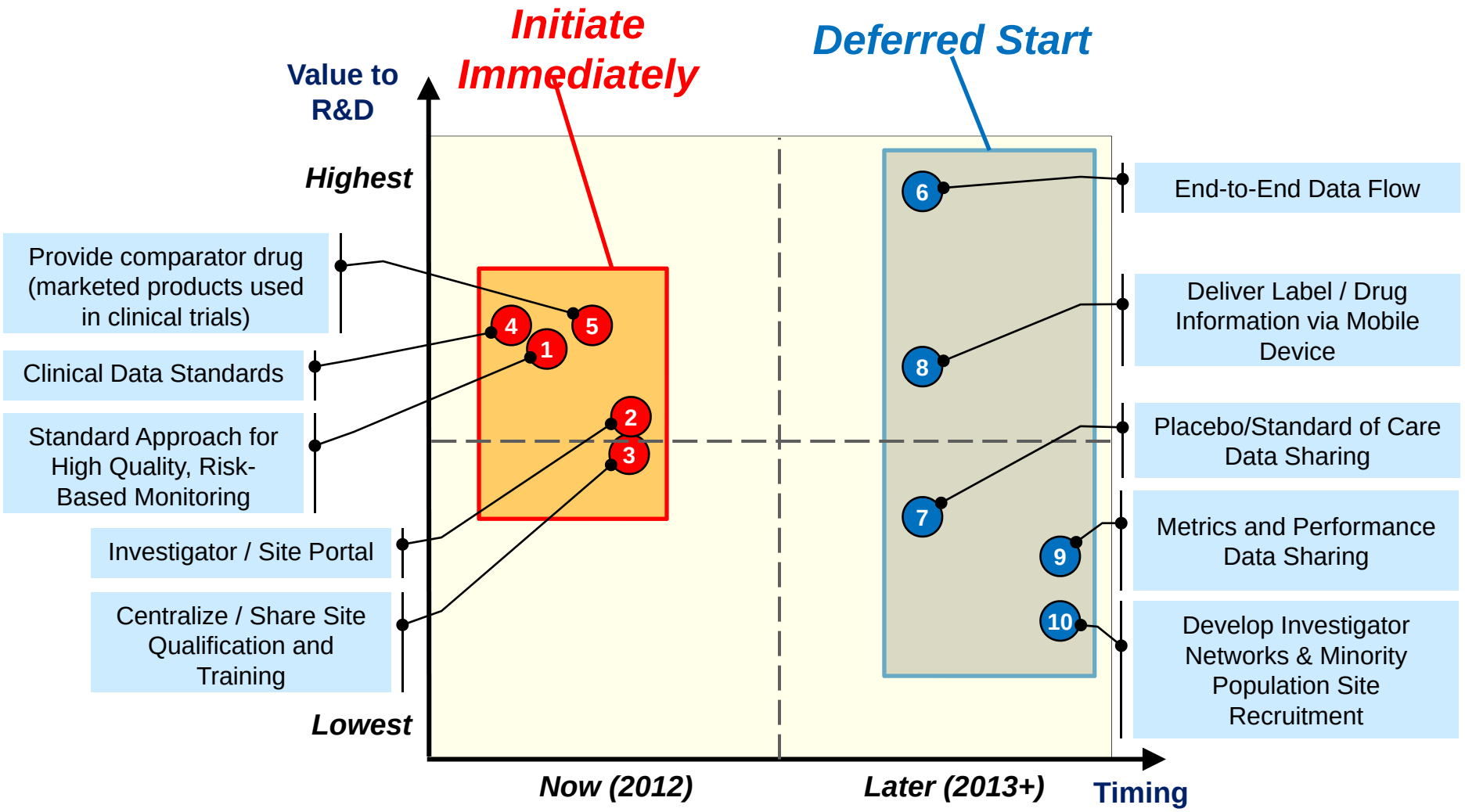

Risk-Based Monitoring
Project Overview

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Description

Develop an industry-wide standard and approach for risk-based monitoring of clinical trials in order to enhance patient safety and ensure the quality of clinical trial data.

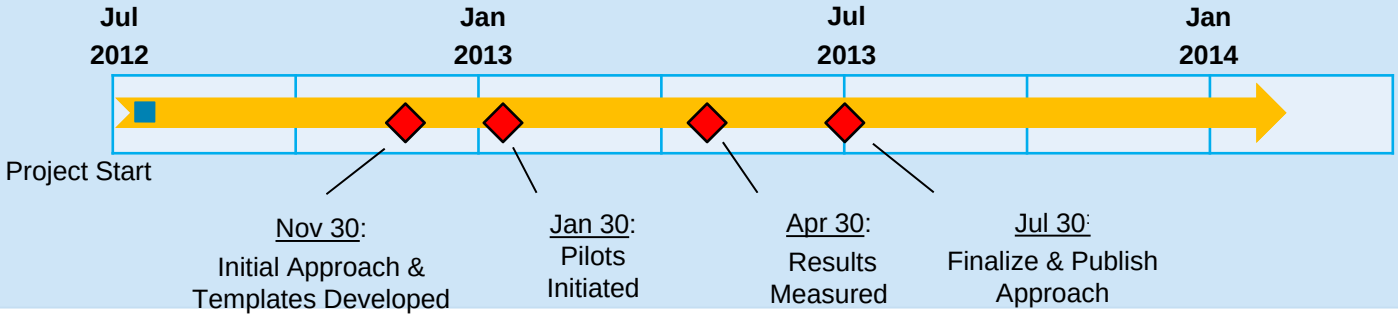
Target Outcomes

- A standard framework and approach for risk based monitoring, including:
  - Common tools & triggers to identify risk
  - Categorization criteria for low, medium and high risk trials
- A validated approach tested through pilot trials and vetted by Regulators
- Raised awareness through publications and conference presentations

Progress-to-Date

- Shared individual company approaches to monitoring
- Formed working teams and set milestones for developing risk based monitoring standards
- Agreed upon assumptions and guiding principles

Project Milestones



Investigator Site Portal

Project Overview

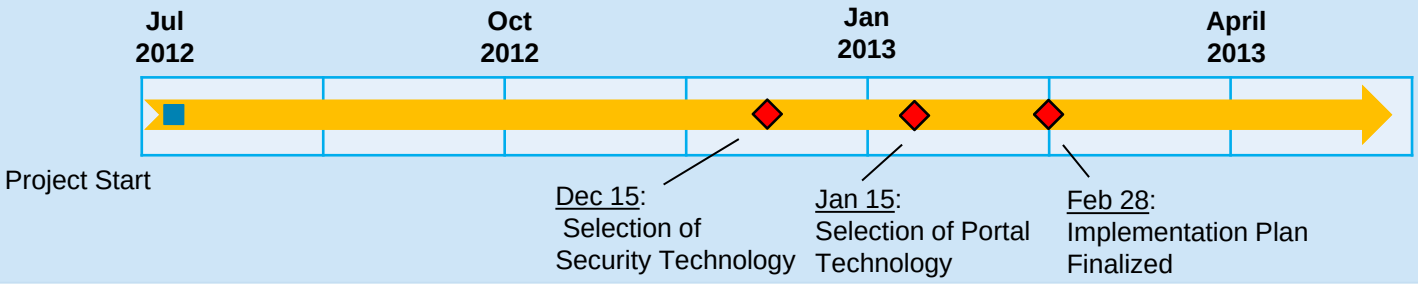
[redacted]

[redacted]

Progress-to-

[redacted]

Project Milestones



Site Qualification & Training

Project Overview

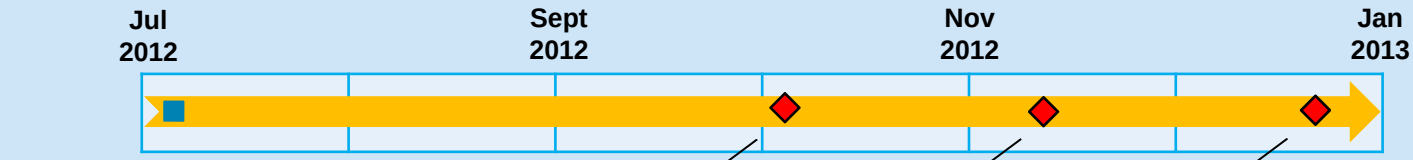
[redacted]

[redacted]

Progress-to-

[redacted]

Project Milestones



Project Start

Oct 30: Requirements Finalized for GCP Training

Nov 30: Finalized Site Qualification Process

Dec 31: Mutual Recognition Agreements

Clinical Data Standards

Project Overview

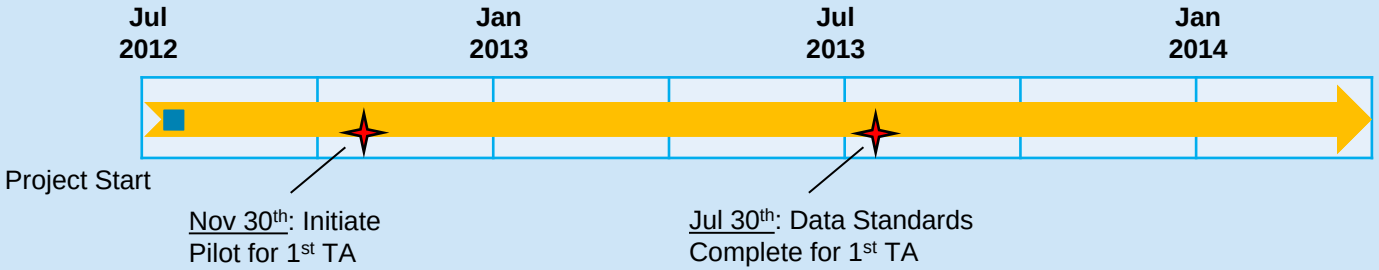
[redacted]

[redacted]

Progress-to-

[redacted]

Project Milestones



Comparator Drugs for Clinical Trials

Project Overview

[redacted]

[redacted]

Progress-to-

[redacted]

Project Milestones