TransCelerate
BIOPHARMA INC.

ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

The Future of R&D Collaboration:
Pre-Competitive Collaboration in Clinical Trial Execution

An introduction to TransCelerate
German CDISC UG Meeting – Leverkusen Feb 26th , 2013

Presentation Outline

- Background
- The Path to Pre-Competitive Collaboration
- Introduction to the new CEO: Dalvir Gill
- Formation of TransCelerate BioPharma Inc.
- Key Accomplishments and Future Milestones

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What you may have heard about us through the press…

The New York Times

Drug Makers Join Efforts in Research

By ANDREW POLLACK
Published: September 19, 2012

Ten of the world's largest pharmaceutical companies said on Wednesday that they would cooperate on research aimed at accelerating drug development, starting with streamlining clinical trials.

PharmaTimes

Companies join forces to improve R&D

Ten pharmaceutical companies have joined together with Accenture to form an organisation to identify and solve the R&D issues facing the industry, and help speed drugs to market

TransCelerate BioPharma Inc. Appoints Dalvir Gill as Chief Executive Officer

PR Newswire

PHILADELPHIA, Dec. 10, 2012 /PRNewswire/ -- ***TransCelerate BioPharma Inc.*** ("***TransCelerate***") today announced that Dalvir Gill, PhD, has been appointed Chief Executive Officer, effective January 1, 2013. Dr. Gill will lead the independent non-profit entity, which was formed by ten healthcare and pharmaceutical companies in September to

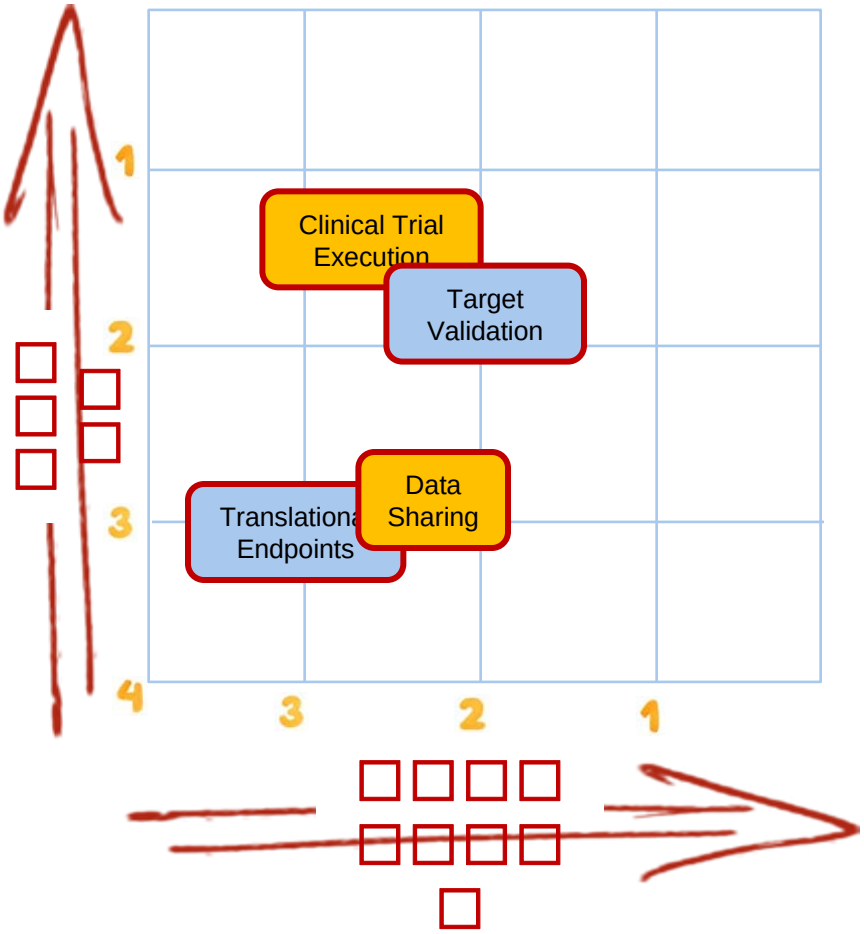
TUESDAY, DECEMBER 11, 2012

Alliance Deal of the Year Nominee: Transcelerate

THE IN VIVO BLOG
BIOPHARMACEUTICAL INDUSTRY INTELLIGENCE AND ANALYSIS
DEAL OF THE YEAR 2012

Key R&D leaders identified Clinical Trial Execution as a key priority area for industry-wide collaboration

Survey Results



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."

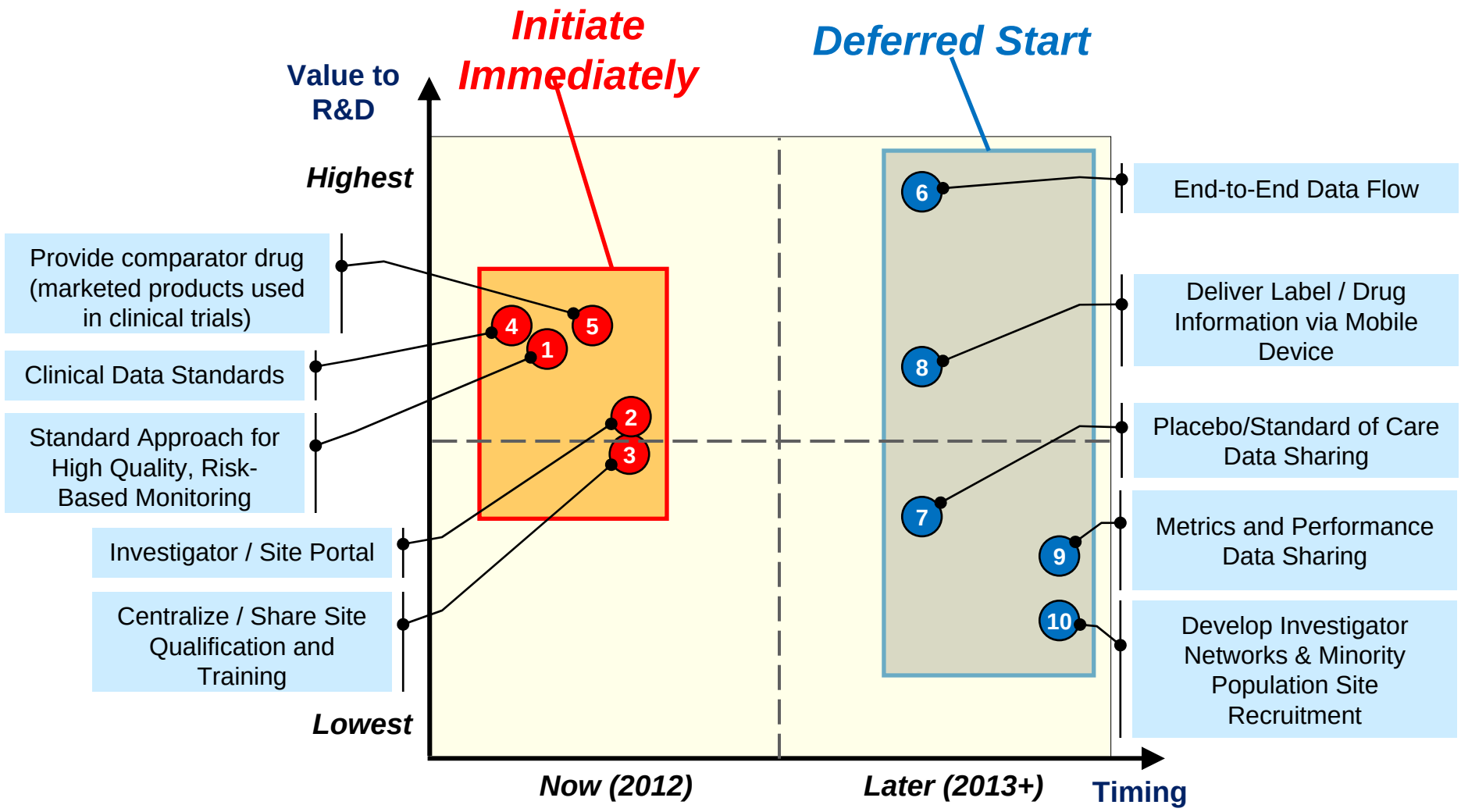
"We have already implemented major changes in clinical operations, but we are interested in more "industrial" trial site execution."

On Doability…

"Requires regulator endorsement."

"Sharing of infrastructure is a major opportunity."

Specific to collaboration, five opportunities in clinical trial execution were prioritized for near term pursuit



The five initiatives share goals of improving quality, patient safety, efficiency and development timelines

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Prioritized Near Term Initiatives

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

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

Objective: Develop a standard framework for targeted, risk based clinical trial monitoring
Benefits: Improvement in data quality and patient safety for clinical trials; reduction in effort expended on low-value activities

2 Shared Site Qualification and Training

Objective: Mutual recognition of GCP training and site qualification between pharmaceutical companies
Benefits: Improved quality of clinical sites and accelerated study start-up times

3 Common Investigator Site Portal

Objective: Establish a single, intuitive interface for investigators used across the industry
Benefits: Ease of use and harmonized delivery of content and services for investigators

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

For the road ahead, TransCelerate appointed Dalvir Gill as the CEO starting 1/1/2013

***Chief Executive Officer*, TransCelerate BioPharma Inc.**

Dalvir Gill, PhD has more than 25 years of drug development experience. Prior to his appointment as CEO of TransCelerate, Dr. Gill was the President of Phase II-IV Drug Development at PharmaNet-i3, an organization specializing in drug development services. In this role, Dr. Gill was responsible for a global business spanning nearly 40 countries.

Dr. Gill earned his BS in Applied Biology from the University of Hertfordshire and his PhD in Pathobiology from the Royal Free Hospital School of Medicine, University of London. He also holds a diploma in the health economics of pharmaceuticals from the executive program of the Stockholm School of Economics. Dr. Gill has presented his research and spoken at numerous conferences and has authored over 30 scientific publications. He also is an elected fellow of the Royal Society of Medicine.

"I am honored to lead this organization and work with the global research and development community to assess, refine and create processes to bring innovative new medicine to the public faster,"

Dalvir Gill, PhD

"Dr. Gill is a recognized industry leader with a proven history of success in the field of drug development. His deep experience across the pharmaceutical industry will help TransCelerate to advance key initiatives and provide solutions that will have measurable impact for patients worldwide."

Garry Neil, MD

To drive the pre competitive collaboration opportunities into implementation, TransCelerate was incorporated

Existing collaboration organizations within the life sciences industry were evaluated for their ability to successfully execute the selected opportunities in clinical trial execution and it was determined that no existing vehicles met the necessary criteria. Therefore a ***dedicated implementation organization*** *will be formed to promote a high-level of member accountability and a results-driven approach.*

The new organization will embody the following defining characteristics:

- ❑ Broad industry membership from Pharma and Biotech
- ❑ Lean, non-profit entity with sufficient funding by member companies
- ❑ High level of member company control and accountability
- ❑ Board of Directors composed of senior R&D leadership
- ❑ Member FTE contributions of experienced and skilled resources

Mission Statement for TransCelerate

TransCelerate BIOPHARMA INC.

*"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."*

The Charter Members of TransCelerate include Major Biopharmaceutical Companies

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

Abbott

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

Johnson & Johnson

Martin Mackay (Board Member)
Head of Science & Technology
Anders Ekblom (Alternate Board Member)
EVP, Global Medicines Development
Sue McHale (Operations Committee)
Executive Director, Global Project Delivery

AstraZeneca

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

Lilly

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

Boehringer Ingelheim

Mikael Dolsten (Board Member)
President of Worldwide R&D
John Hubbard (Alternate Board Member)
SVP Development Operations
Craig Lipset (Operations Committee)
Head of Clinical Innovation

Pfizer

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

Bristol-Myers Squibb

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

Roche

Patrick Vallance (Board Member)
President, Pharmaceuticals R&D
Lynn Marks (Alternate Board Member)
SVP, Clinical Platforms & Sciences
Pete Milligan (Operations Committee)
Director, Lead for SCD

gsk GlaxoSmithKline

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

SANOFI

The intent is not to recreate, but rather partner with existing collaborations closely aligned to the projects

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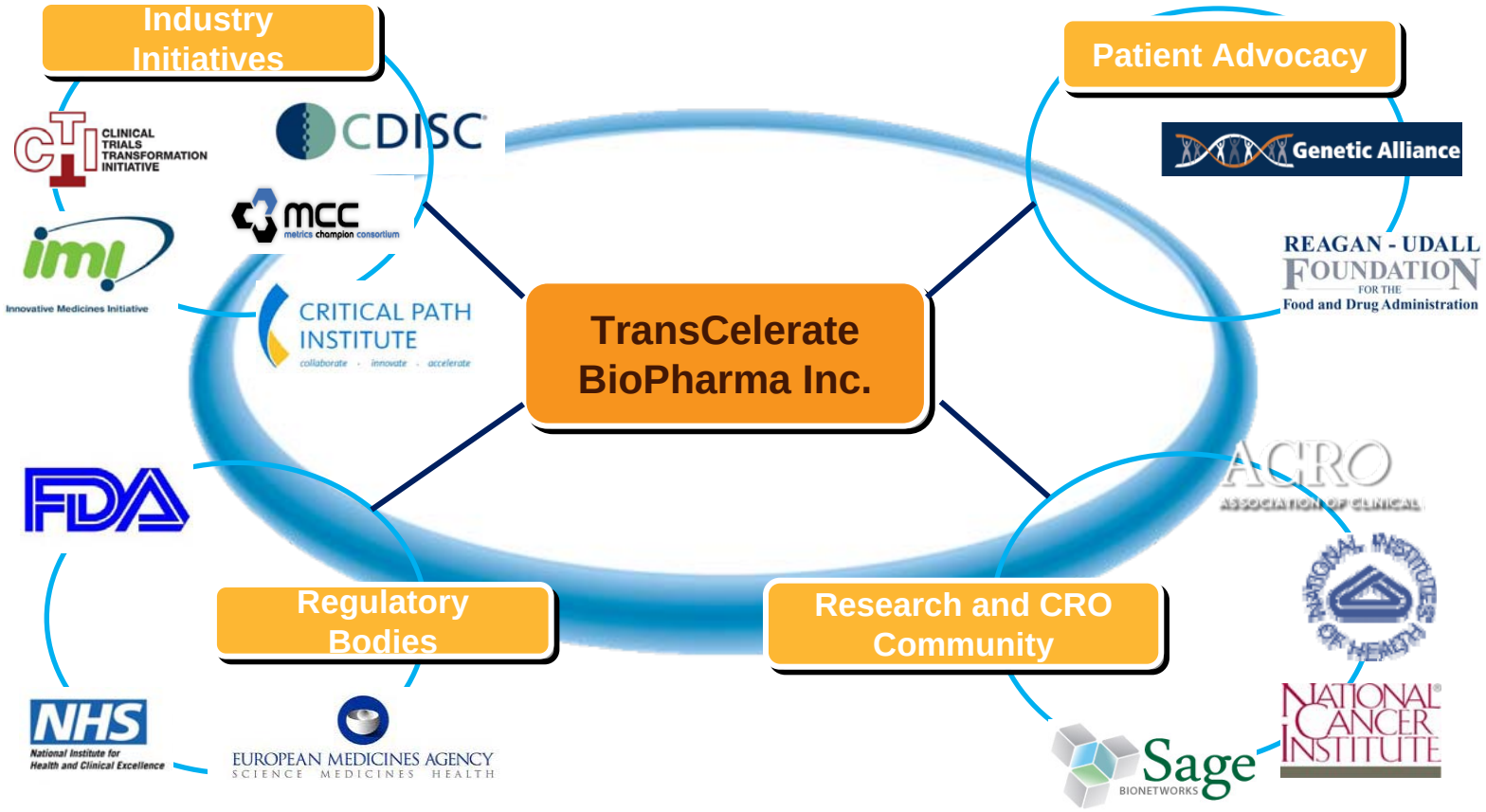
External Engagement with the Larger Ecosystem

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



TransCelerate has made key accomplishments to date and anticipates a successful year in 2013

	Top 5 Accomplishments achieved in 2012
1	Mobilized 10 companies for the initiation of 5 key projects
2	Designed the supply model for the distribution of comparator drugs
3	Initiated the asthma pilot for clinical data standards
4	Established the criteria for industry GCP training and process for mutual recognition
5	Established the industry framework and approach for risk based monitoring

	Key Milestones planned for 2013
1	Kick-off the pilot for industry distribution of comparator drugs
2	Initiate the standards development of 6 additional therapeutic areas
3	Develop the industry framework and approach for site qualification
4	Conduct and assess the pilot for risk based monitoring
5	Deploy the first release of the Shared Site Portal

Some abbreviations …

- **BRIDG**: The **B**iomedical **R**esearch **I**ntegrated **D**omain **G**roup (**BRIDG**) Model
- **SHARE:** The CDISC **S**hared **H**ealth **A**nd Clinical **R**esearch **E**lectronic Library (**CDISC SHARE**)
  - Global, accessible electronic library, which through advanced technology, enables standardized data element definitions and richer metadata that can be used in software applications and research studies to improve biomedical research and its link with healthcare
  - SHARE metadata is envisioned to help find, understand and use clinical metadata efficiently
- **CFAST**: **C**oalition **F**or **A**ccelerating **S**tandards and **T**herapies
  - Formed by the Clinical Data Interchange Standards Consortium (CDISC) and the Critical Path Institute (C-Path) "to accelerate clinical research and medical product development by creating and maintaining data standard, tools and methods for conducting research in therapeutic areas that are important to public health."
  - CFAST was officially launched in October 2012. CFAST activities – e.g. development of data standards and the implementation of these standards to accelerate the development and review of new therapies and to enhance the information that can be obtained from streamlining the sharing, aggregation and analysis of clinical research data
  - CFAST is working with FDA, TransCelerate, the Innovative Medicines Initiative (IMI), ACRES, other partners and countless volunteers in this endeavor

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Thank you
For your attention !