BioCelerate

Luncheon & Overview:

BioCelerate SEND Harmonization Initiative

Solutions to Enable Cross-Study Analysis

March 13, 2019
Society of Toxicology Annual Meeting
Baltimore, MD, USA

BioCelerate Team Introductions

Thomas Bjerregaard
Toxicology Specialist, CDISC SEND Expert (Novo Nordisk)
Initiative Team Member (BioCelerate)

Mark Carfagna
Senior Research Advisor, Toxicology (Eli Lilly)
Initiative Team Member (BioCelerate)

Tamio Fukushima
Director (Shionogi)
Initiative Team Member (BioCelerate)

William Houser
Principal Scientist (Bristol-Myers Squibb)
SEND Team Leader (CDISC)
SEND Harmonization Lead (BioCelerate)

Kelsey Jakee
Director of Portfolio (BioCelerate)
Principal Consultant, Life Sciences (PA Consulting)

Raja Mangipudy
Executive Director, Toxicology (Bristol-Myers Squibb)
Data Sharing Initiative Lead (BioCelerate)

Todd Page
Director, Toxicology (Eli Lilly)
Nonclinical Study Optimization Initiative Lead (BioCelerate)

Cheryl Sloan
Application Manager & Research Scientist (Bristol-Myers Squibb)
Initiative Team Member (BioCelerate)

We Are BioCelerate

Subsidiary of **TransCelerate BioPharma, Inc.**, a not-for-profit entity created to foster collaboration

Mission to identify, develop and deliver industry initiatives aimed at making **nonclinical R&D** more effective

Improve **data-driven decision making**

Broaden industry **knowledge base**

Improve **quality** of study execution

Enable new process and cost **efficiencies**

Our presence, impact & engagement is worldwide

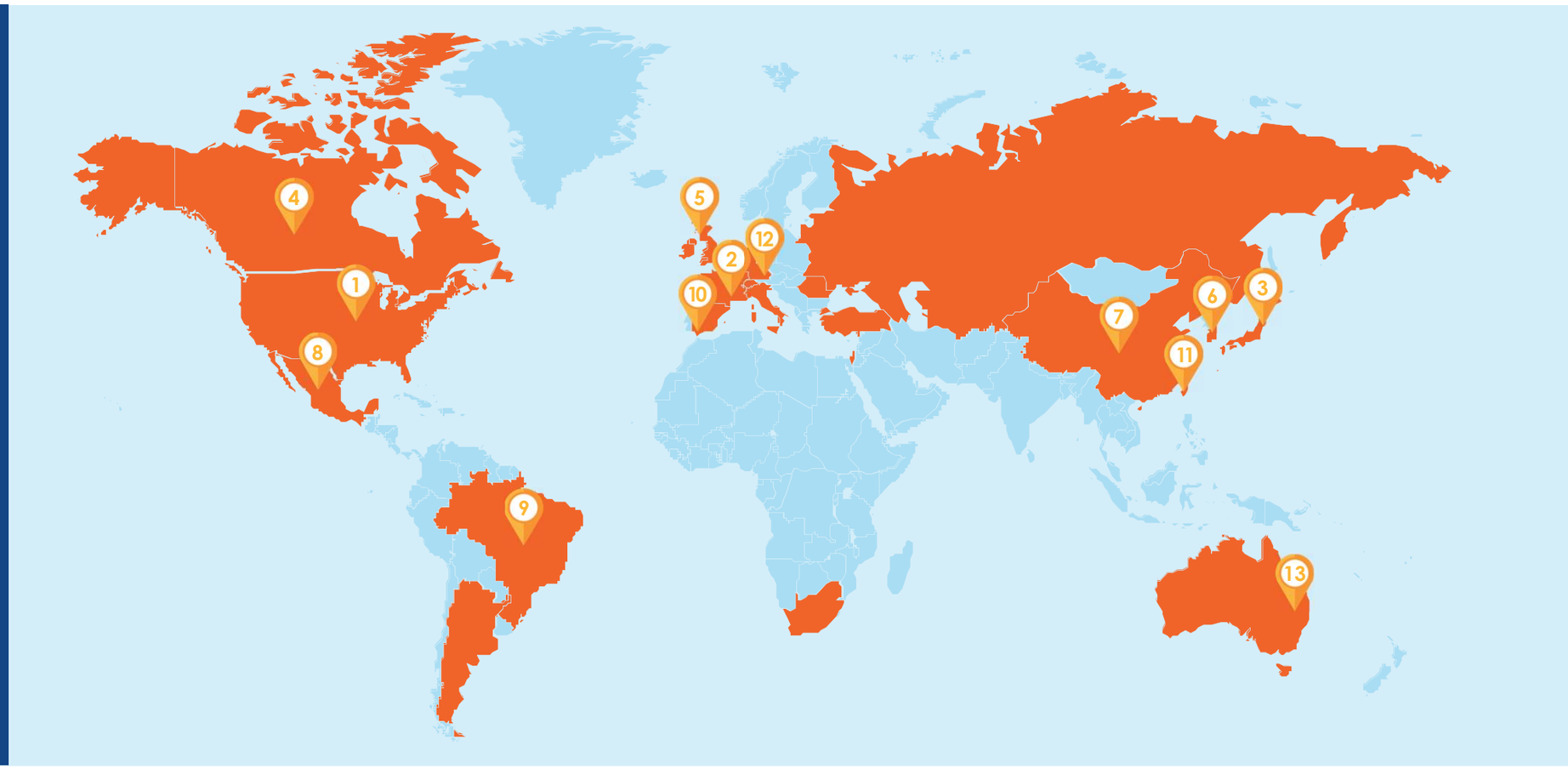
Our Country Network spans

22 COUNTRIES,

and

13 GLOBAL REGULATORY AUTHORITIES

have engaged with TransCelerate.



1 FDA 2 EMA 3 PMDA 4 Health Canada 5 MHRA 6 MFDS 7 CFDA 8 COFEPRIS 9 ANVISA 10 AEMPS 11 TFDA 12 BfArM 13 TGA

We are currently focused on two major initiatives

Initiative 1: Data Sharing

Toxicology & Background Control Data Sharing

Designed to empower participants to make **data-driven decisions** on compound progression based on an improved **understanding of on- and off-target toxicity**. Output includes:

- Development of **DataCelerate™**, a data sharing platform initially enabling sharing, search, and visualization of de-identified toxicology and background control data

Status:

Explore Design **Deliver** **Maintain**

Initiative 2: Nonclinical Study Optimization

Common Templates for Nonclinical Studies

Seeking **efficiencies** for Sponsors, CROs and others, this initiative is pursuing the development of templates for nonclinical studies with input from affected stakeholders. Common templates will help minimize cost, errors, and improve overall **quality** in the interpretation and execution of studies. Initial output includes:

- Toxicology study **protocol template** (focusing on FIH-enabling, 28-day studies)

Status:

Explore **Design** Deliver Maintain

SEND Implementation for Study Analysis

The **CDISC SEND** format is growing in adoption across industry, but variability in its use/implementation results in inconsistent study data packages and reports, making **cross-study analyses** difficult. Initial output includes:

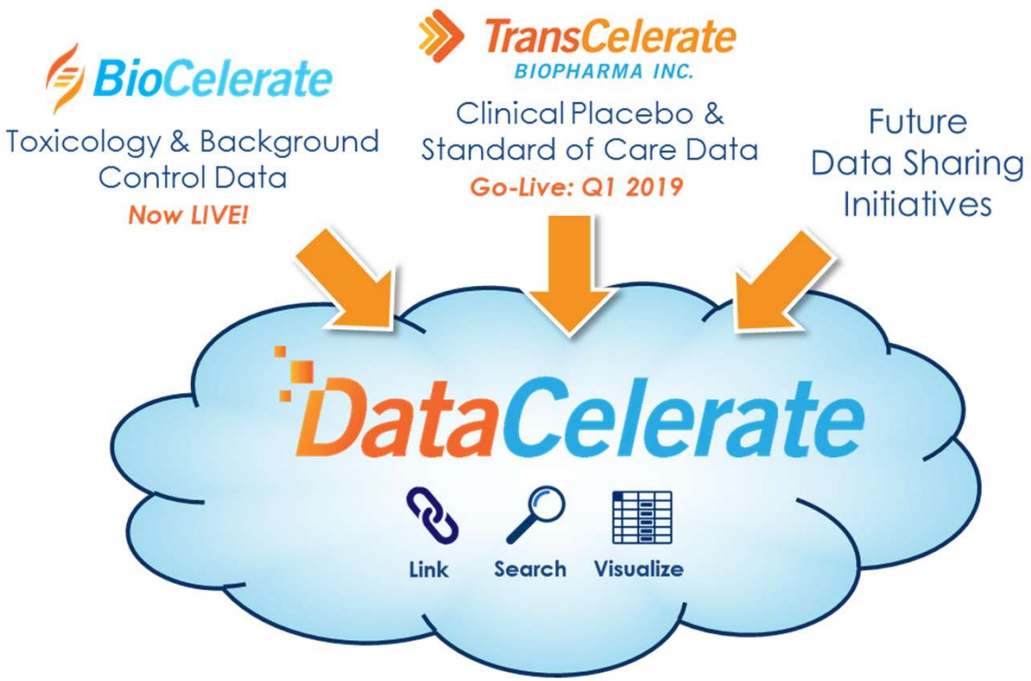
- Examination of **implementation variabilities** for CDISC SEND and **challenges** in the use of SEND data packages to facilitate cross-study comparisons

Status:

Explore Design Deliver Maintain

Our work in data sharing: DataCelerate

DataCelerate will be used to aggregate and analyze nonclinical and clinical information to improve drug development efficiency and bring new medicines to patients faster.



One platform versus many

A modular, single sign-on data repository for all nonclinical and clinical data sharing initiatives across TransCelerate & BioCelerate

Connecting datasets, enabling insights

Long term, the platform will enable translational insights by linking associated datasets across compounds and across the R&D continuum, where possible

SEND Implementation for Study Analysis

Our goal is to prepare recommendations for structuring SEND datasets to enable various single-study and cross-study analysis use cases.

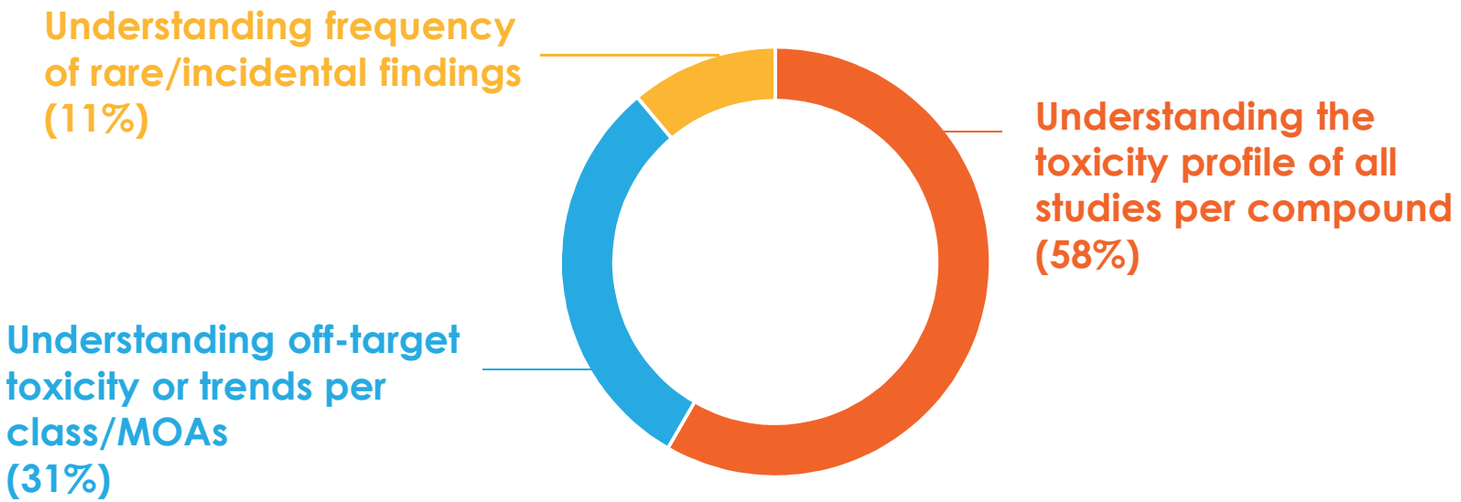
Analysis Use Case Examples

Understanding the **toxicity profile** for all studies performed for one compound, as well as understanding the **effects of longer exposure**	Understanding **off-target toxicity** / multiple compounds binding to the same target as well as understanding **trends for a class** of compounds or MOAs	Understanding the **effects of vehicles** that might be used on different studies	Understanding **frequency of rare and incidental findings** from background control studies	Enabling application of SEND data within **QSAR**

Identified use cases apply to cross-study analysis performed in any number of data warehousing and visualization solutions, including DataCelerate™

What have we learned from stakeholders so far?

Which cross-study analysis use case do you think is <u>most</u> valuable using harmonized SEND datasets?
n = 36



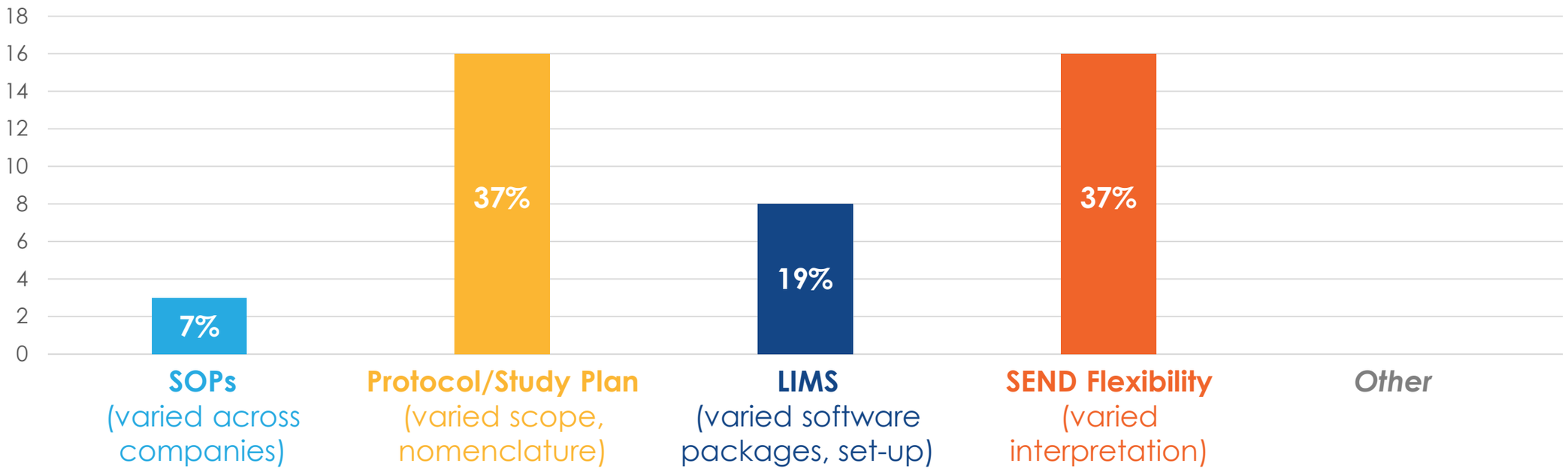
Not selected as a <u>most</u> valuable use case:

- Understanding the effects of vehicles
- Enabling application of SEND data within QSAR

** % response totals from polls fielded across two webinar sessions on March 5, 2019 (10 AM ET & 8 PM ET). Registrants of the webinars voluntarily self-identified as either a Research Sponsor/BioPharma (45%), Tech Vendor (16%), CRO (12%), Other Service Provider/Vendor (11%), Health Authority (9%), or Industry Group/Consortium (7%). Registrant geographies included North America (64%), Asia (26%), Europe (9%), and Central/South America (1%).*

What have we learned from stakeholders so far?

Where do you think the <u>biggest</u> drivers of variability across SEND datasets originate from?
n = 43



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We are proposing a collaborative, four-stage approach to develop future solutions

Proposed Initiative / Public Consultation Stages: Applying SEND to Study Analysis

Involvement Requested From:

- BioPharma / Sponsors
- CROs
- CDISC
- Tech / Vendors
- Health Authorities

Today's Meeting

Lunch and Table Introductions (11:25 – 11:45 AM)

Small Group Discussion at Tables (11:45 – 12:15 PM)

- *Value and Challenges of SEND Harmonization*

Full Group Discussion Re-cap (12:15 – 12:45 PM)

Closing and Next Steps (12:45 – 01:00 PM)

Study Analysis Use Cases for SEND

Analysis Use Case Examples

Understanding the **toxicity profile** for all studies performed for one compound, as well as understanding the **effects of longer exposure**	Understanding **off-target toxicity** / multiple compounds binding to the same target as well as understanding **trends for a class** of compounds or MOAs	Understanding the **effects of vehicles** that might be used on different studies	Understanding **frequency of rare and incidental findings** from background control studies	Enabling application of SEND data within **QSAR**
58% Respondents who consider this a 'most valuable' use case	**31%** Respondents who consider this a 'most valuable' use case		**11%** Respondents who consider this a 'most valuable' use case	

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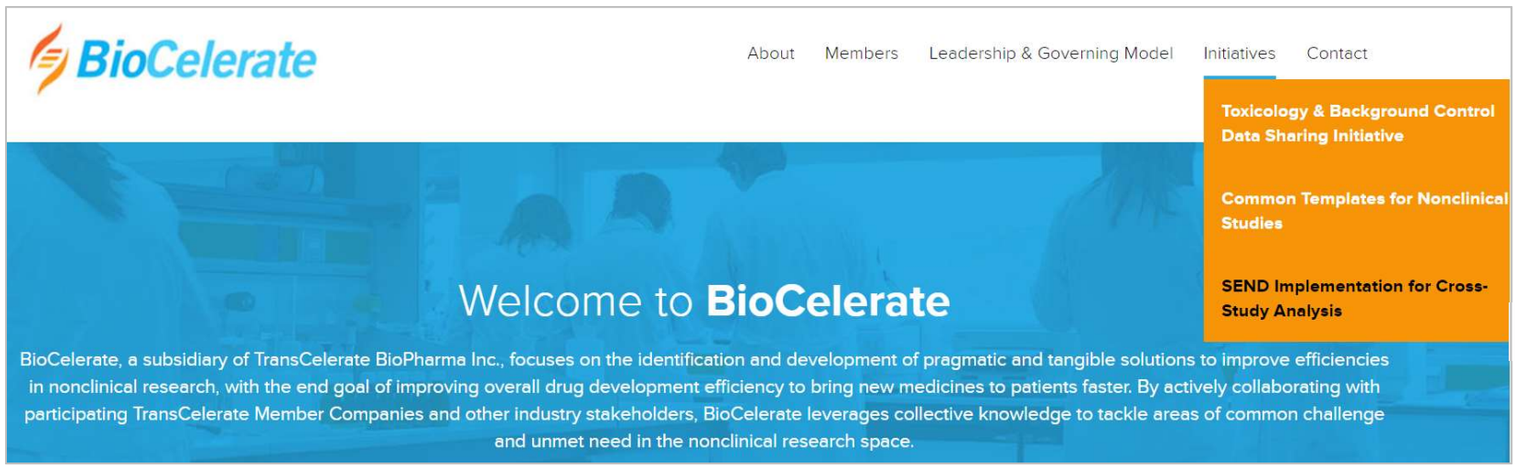
How You Can Get Involved

Visit us online! https://www.transceleratebiopharmainc.com/biocelerate/



- Review the SEND Public Consultation Memo
- Sign up for updates through our mailing list
- Register for upcoming events (additional public discussions expected in 2019)

Thank you

Visit us for more information:

http://www.transceleratebiopharmainc.com/biocelerate/

TransCelerate BIOPHARMA INC.

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