TransCelerate?

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Nationell samverkan

Några exempel där nationell samverkan över företagsgränser/kommuner och landsting/ myndigheter medfört betydande förenklingar vid genomförandet av kliniska prövningar i Sverige.

- **Multicenteravtal vid klinisk prövning som inkluderar vävnadsprover**
- **10 Nationella mallar**

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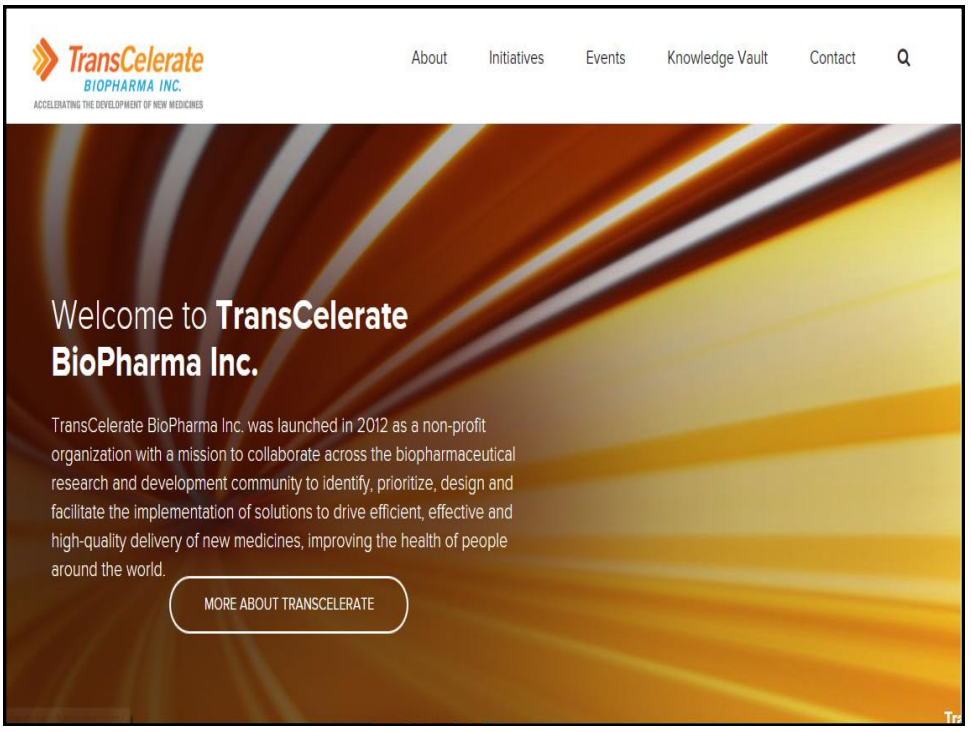
BIOPHARMA INC.

ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

http://www.tranceleratebiopharmainc.com



ABOUT US

TransCelerate has unique attributes — leadership participation from the world's leading biopharmaceutical organizations; Robust partnerships with industry organizations such as ACRO (Association of Clinical Research Organizations), CFAST (Coalition For Accelerating Standards and Therapies), CTTI (Clinical Trials Transformation Initiative) and SCRS (Society for Clinical Research Sites); and collaboration and insight from Global Regulatory Authorities — EMA (European Medicines Agency), FDA (U.S. Food and Drug Administration) and PMDA (Pharmaceuticals and Medical Devices Agency) — that enable us to create value for the industry.

We harness these attributes as we focus on five strategic priorities:

Improve the Site Investigator Experience	Improve the Site Investigator Experience as they work with Sponsors to execute Clinical Trials.
Facilitate the Sharing of Information	Facilitate the sharing of clinical trial related information as appropriate amongst industry stakeholders, focused on exchanges of information that would enable the industry to capture efficiencies.
Enable Harmonization of Clinical Trial Processes	Enable the industry to move toward greater harmonization of clinical trial processes to facilitate the advancement of technologies and processes within the broader clinical ecosystem.
Enhance Sponsor Efficiencies	Through collaboration, streamline redundant sponsor activities to reduce investigator and Patient burden, while refocusing resources to drive and deliver innovative drugs to patients faster and safely.
Improve the Patient Experience	Improve the Patient Experience by enabling earlier access to well run clinical studies.

20 Pharmaceutical Companies providing their best talent to collaborate and develop solutions to overcome industry inefficiencies

** 10 Pharmaceutical Companies chartered TransCelerate and 9 additional companies joined in 2013*

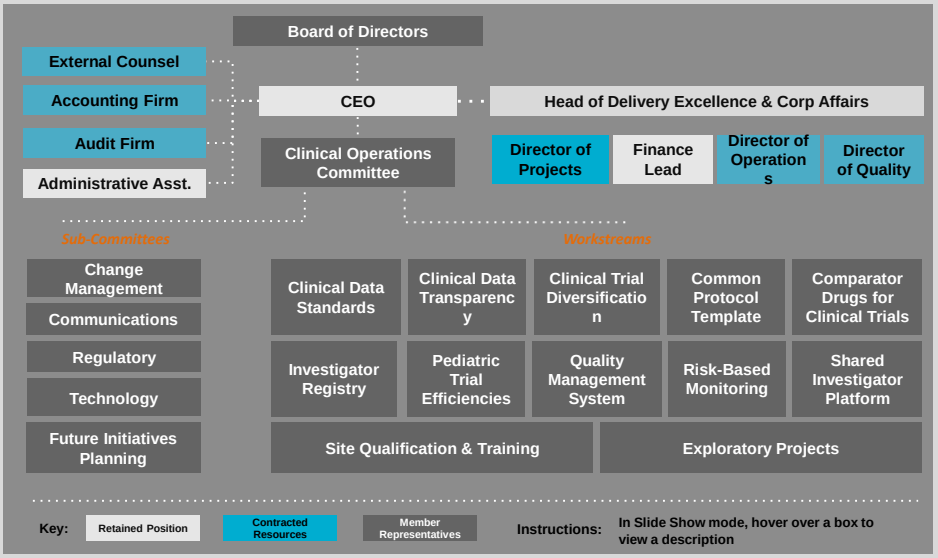
Strategically focusing engagement efforts with selected key stakeholder groups

To Drive Collaboration Opportunities Into Implementation, TransCelerate Was Incorporated

*The new organization embodies 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

A Flat Organization Structure Has Been Developed To Manage Projects And Operational Activities



Chair of The Board

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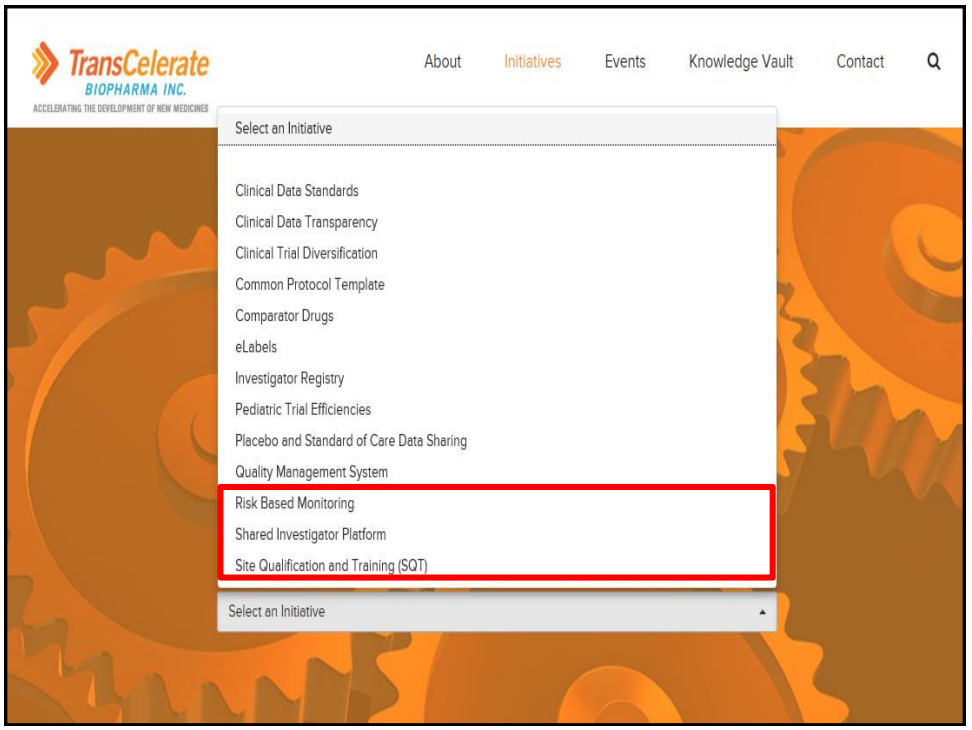
"We're collaborating to crack the common drug development challenges to make the clinical trial process more efficient and get new medicines to patients faster."

Briggs W. Morrison MD, Executive Vice President GMD and Chief Medical Officer



Site Qualification and Training (SQT)

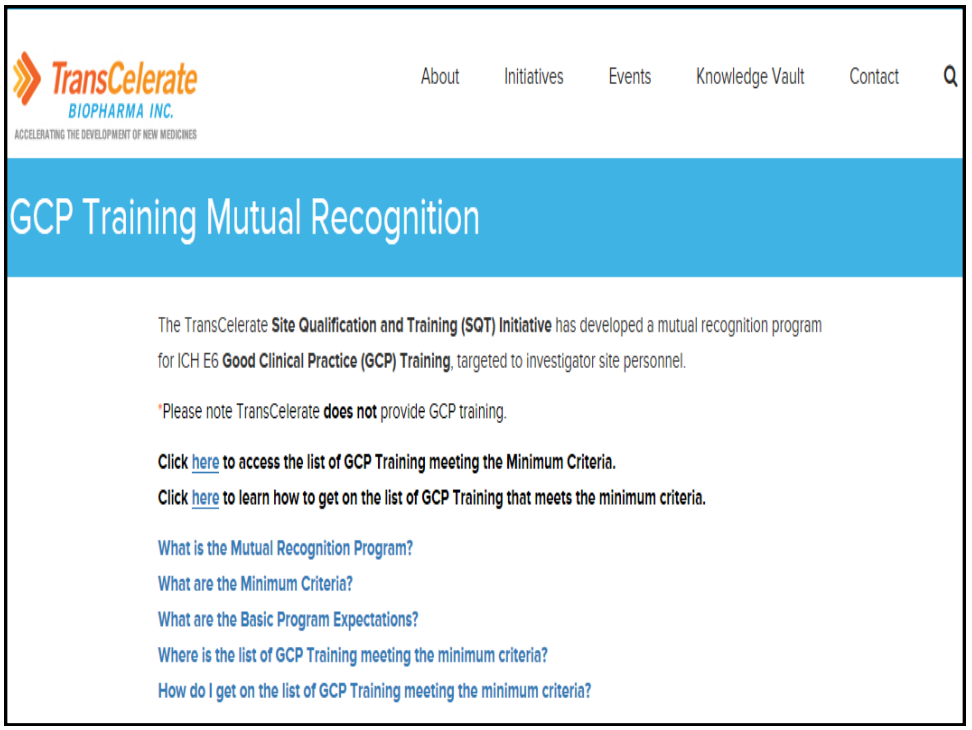
Rationale

Traditionally, clinical trial investigators and sites are required to complete – for each company, and often, per trial – questionnaires, forms and training courses to prepare for participation in trials. The goal of this initiative is to enhance and simplify the clinical trial Site Qualification and Training (SQT) process by creating common tools and resources that reduce time spent on non-study specific tasks and therefore allow for more focus on protocol-related work.

The SQT Initiative collaborates with TransCelerate Member Companies, investigator sites, CROs and regulatory agencies to achieve the goal of enhancing and simplifying clinical trial SQT processes and to reduce administrative burden on sites.

Target Outcomes:

- Minimum criteria for mutual recognition of GCP training
- Self-attestation process for external GCP training providers
- Common forms to collect generic site information
- Informational Programs for investigator site personnel



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GCP Training Mutual Recognition

The TransCelerate **Site Qualification and Training (SQT) Initiative** has developed a mutual recognition program for ICH E6 **Good Clinical Practice (GCP) Training**, targeted to investigator site personnel.

*Please note TransCelerate **does not** provide GCP training.

Click here to access the list of GCP Training meeting the Minimum Criteria.

Click here to learn how to get on the list of GCP Training that meets the minimum criteria.

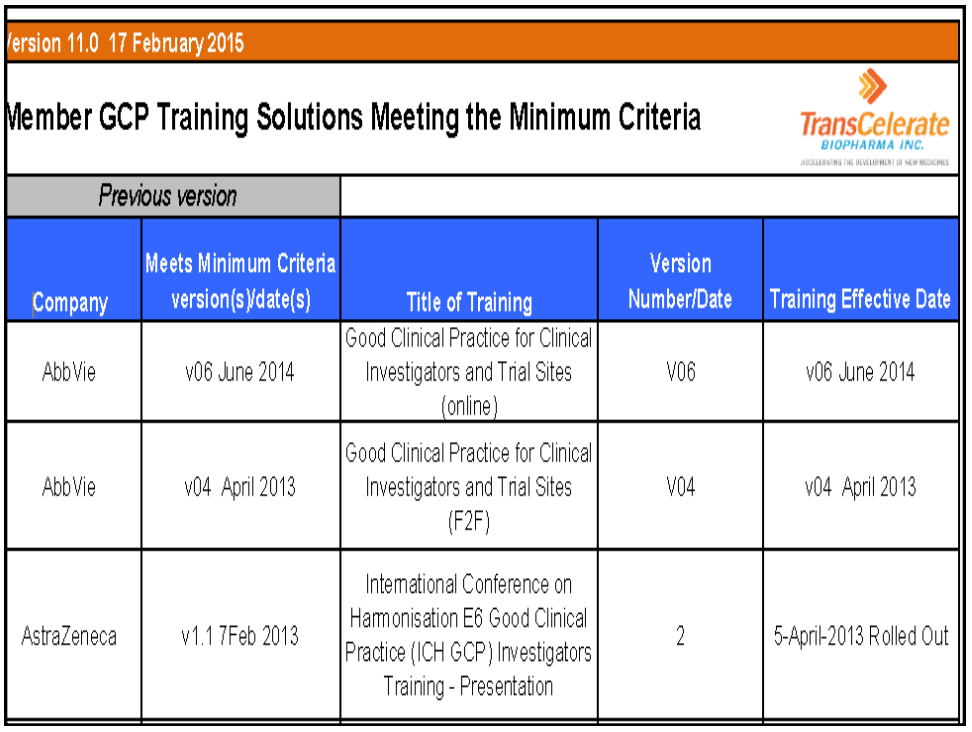
What is the Mutual Recognition Program?

What are the Minimum Criteria?

What are the Basic Program Expectations?

Where is the list of GCP Training meeting the minimum criteria?

How do I get on the list of GCP Training meeting the minimum criteria?



Version 11.0 17 February 2015

Member GCP Training Solutions Meeting the Minimum Criteria

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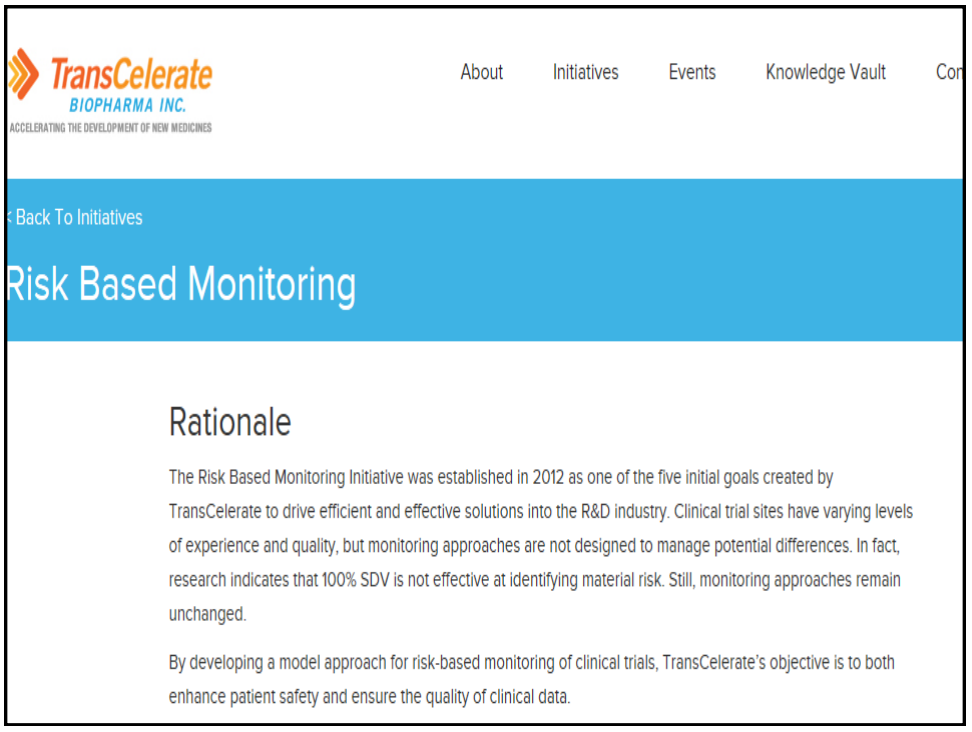
Previous version				
Company	Meets Minimum Criteria version(s)/date(s)	Title of Training	Version Number/Date	Training Effective Date
AbbVie	v06 June 2014	Good Clinical Practice for Clinical Investigators and Trial Sites (online)	V06	v06 June 2014
AbbVie	v04 April 2013	Good Clinical Practice for Clinical Investigators and Trial Sites (F2F)	V04	v04 April 2013
AstraZeneca	v1.1 7Feb 2013	International Conference on Harmonisation E6 Good Clinical Practice (ICH GCP) Investigators Training - Presentation	2	5-April-2013 Rolled Out

Forms for Investigator Sites

Forms	What Is It?	Value of Using	Related Guidance Documents
Financial Disclosure Form (FIDS)	Form intended for use by Clinical Investigators to disclose their financial interests for the period of time he or she participated in the study and for one year following the end of his or her participation in the study (as required by the U.S. Code of Federal Regulations 21CFR54) to the Study Sponsor.	• One form for sites and member companies to use • Consistent definition of the tasks • Less risk for errors	N/A
Protocol Level Informed Consent Tracking Log Site Specific Informed Consent Tracking Log	Protocol and Site Level Informed Consent Logs for Member Companies and sites to enable a more meaningful and well informed consent dialogue with patients.	• Transparency to the protocol and site level changes to inform sites, member companies and auditors • Enable more robust discussion with patients during re-consent	Protocol and Site Level Informed Consent Logs Guidance
Site Profile Form	A questionnaire, or "Site Profile Form," for collecting site capability information.	• Avoids duplication of work for sites and members • Less administrative work will free up time for focusing on the critical aspects of the study • Improves quality through consistency	Site Profile Form Guidance Site Profile Form FAQs
Curriculum Vitae Template	A template for Curriculum Vitae (CV)	• One consistent approach for all sites and member companies • Reduce confusion and administrative burden	Curriculum Vitae (CV) Template Guidance Curriculum Vitae (CV) Template FAQs
Site Signature and Delegation of Responsibilities Log	One delegation log for sites to use with consistent named tasks and clear instructions.	• One template for all sites and members to use with consistent definition of the tasks • Reduce confusion and administrative burden for the sites • Improve the quality	Site Signature and Delegation of Responsibilities Log Guidance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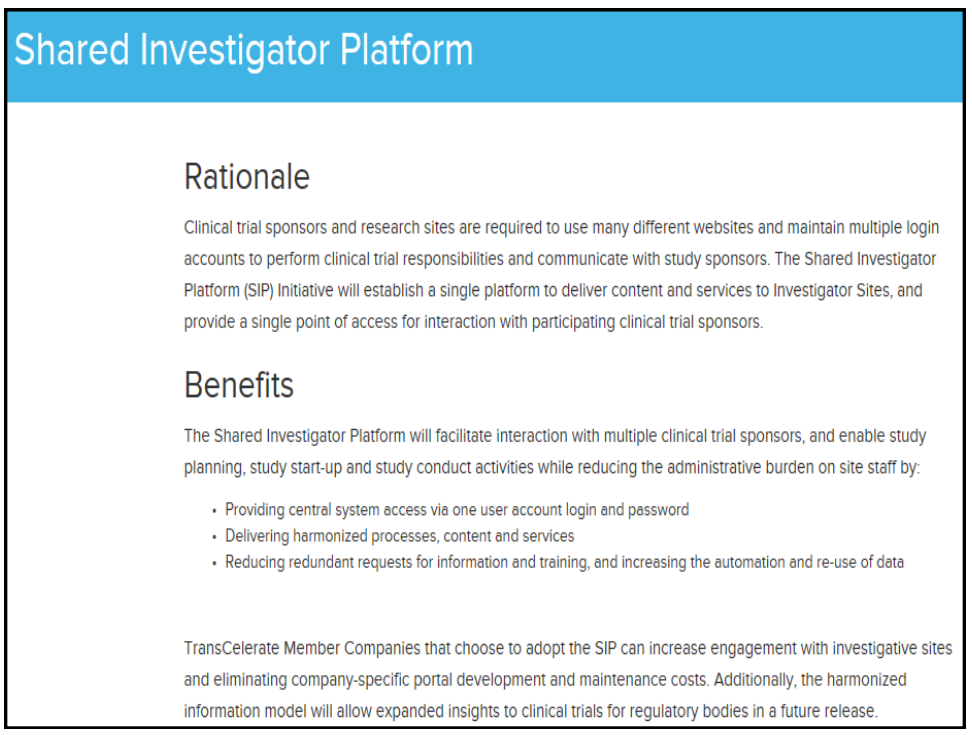
Risk Based Monitoring
Rationale
The Risk Based Monitoring Initiative was established in 2012 as one of the five initial goals created by TransCelerate to drive efficient and effective solutions into the R&D industry. Clinical trial sites have varying levels of experience and quality, but monitoring approaches are not designed to manage potential differences. In fact, research indicates that 100% SDV is not effective at identifying material risk. Still, monitoring approaches remain unchanged.
By developing a model approach for risk-based monitoring of clinical trials, TransCelerate's objective is to both enhance patient safety and ensure the quality of clinical data.


Shared Investigator Platform
Rationale
Clinical trial sponsors and research sites are required to use many different websites and maintain multiple login accounts to perform clinical trial responsibilities and communicate with study sponsors. The Shared Investigator Platform (SIP) Initiative will establish a single platform to deliver content and services to Investigator Sites, and provide a single point of access for interaction with participating clinical trial sponsors.
Benefits
The Shared Investigator Platform will facilitate interaction with multiple clinical trial sponsors, and enable study planning, study start-up and study conduct activities while reducing the administrative burden on site staff by:
• Providing central system access via one user account login and password
• Delivering harmonized processes, content and services
• Reducing redundant requests for information and training, and increasing the automation and re-use of data
TransCelerate Member Companies that choose to adopt the SIP can increase engagement with investigative sites and eliminating company-specific portal development and maintenance costs. Additionally, the harmonized information model will allow expanded insights to clinical trials for regulatory bodies in a future release.

In the first 2 years, TransCelerate accomplished the following:

- Engaged Industry
- Established Mutually Recognized GCP Training
- Published Risk-Based Monitoring Position Paper
- Launched SHARE Environment and Published Data Standards User Guides
- Completed Numerous Comparator Product Transactions
- Named Cognizant as Shared Investigator Platform Vendor