



TransCelerate
BIOPHARMA INC.

e-Labels

February 16, 2016

Agenda

TransCelerate - what is its mission and achievements

TransCelerate eLabel accomplishments and upcoming deliverables.

Points to consider prior to implementation of eLabels within your company

eLabels as the foundation for additional functionality

Text Here

TransCelerate is a Non-profit Entity Created to Drive Industry Collaboration in R&D

Our vision

To improve the health of people around the world by accelerating and simplifying the research and development of innovative new therapies.

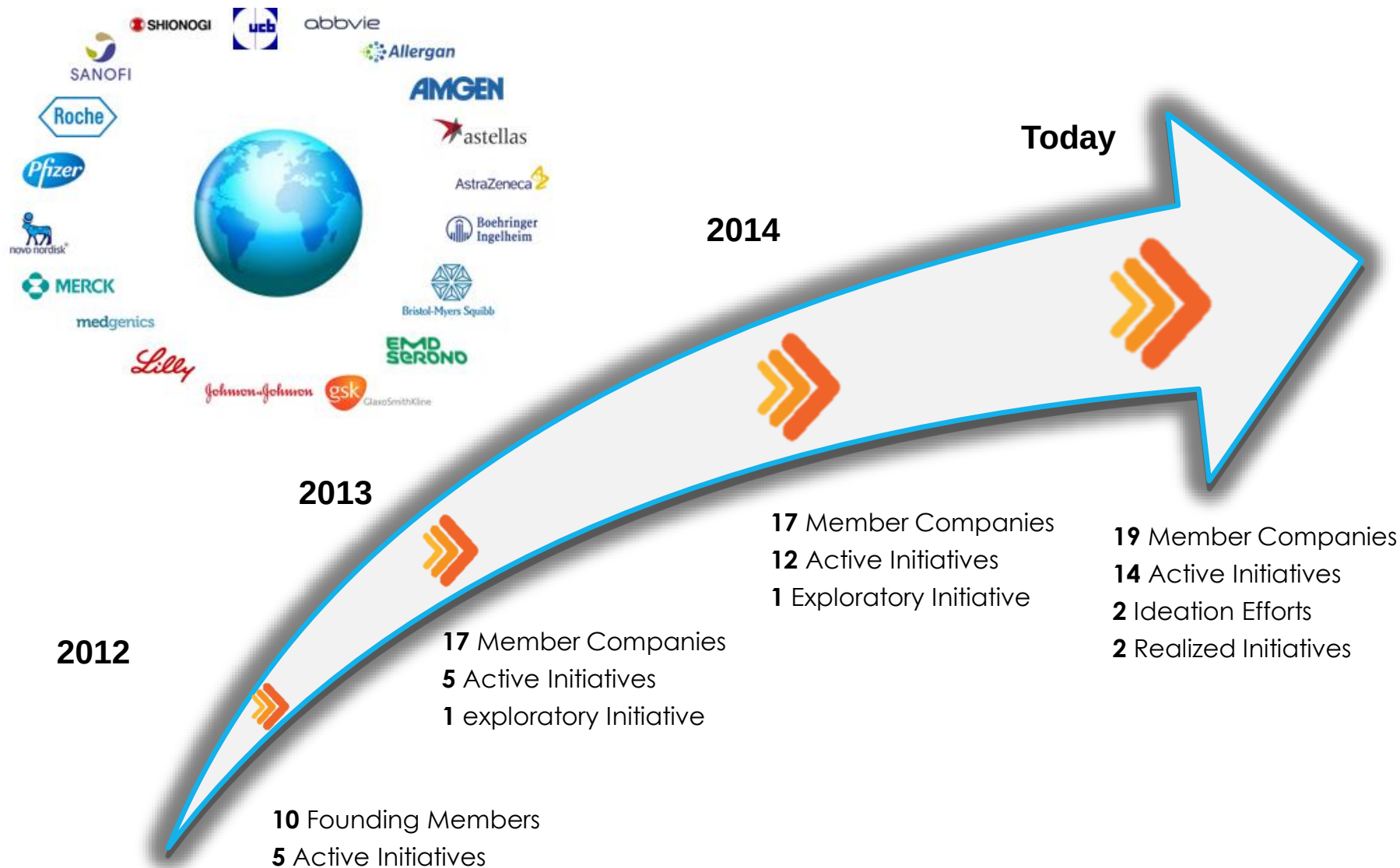
Our mission

To collaborate across the global research and development community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high quality delivery of new medicines.

Our core values

- + Quality
- + Transparency & Openness
- + Trust & Integrity
- + Collaboration
- + Courage

TransCelerate Today :- 19+ Organizations & 14 Active Initiatives



TransCelerate Strategic Priorities



Improve the Site Investigator Experience

Improve the Site Investigator Experience as they work with Sponsors to execute Clinical Trials.



Facilitate Information Sharing

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 a better informed patient and improving study participation.

TransCelerate's Portfolio of Initiatives

TransCelerate's Portfolio of Initiatives focus on Quality, Patient Safety, and Accelerated Development Timelines.



e-Labels Workstream Overview

What does this workstream do?

This workstream will help the industry progress on the journey to digitally supported, patient-centric clinical supply chains. The main output is not an e-Labeling system, but an implementation toolkit to facilitate uptake in the industry.

What is the vision?

Act as a catalyst for clinical supply chain transformation, enhanced patient utility, reduced clinical labeling timelines and costs, promotion of consistent, up-to-date information and coordinated, effective health authority engagement.

What is the approach?

- » Prepare implementation toolkit to facilitate voluntary, modular adoption of e-Labeling.
- Analyze global regulatory environment, create a health authority engagement strategy, and coordinate health authorities.
- Develop technical plan and charter for e-Labels proof of concepts.

e-Labels Addresses Common Pain Points and Benefits Stakeholders Across the Industry

Actual pain points and benefits may vary by member company

	Pain Points		Stakeholder Benefits
Patients 	• Find low usefulness from booklet labels: Few are opened, limited space and small fonts • Cumbersome on devices	»	• Enhanced utility of clinical labels and potential for better compliance, e.g.: ◦ Dosing video ◦ Supplements to communication ◦ Rapid communication
Sites 	• Variation in labeling approaches across the industry	»	• Rapid access to up-to-date information • Greater consistency in Labeling approaches
Health Authorities 	• New labeling technology has surpassed regulations • Need to advance public health by accelerating innovation	»	• Ensures latest information available for patients • Ties into broader digital and innovation strategies
Sponsors 	• Many companies want more flexible, responsive solutions • Greater geographic diversity • Current solutions are occasionally on critical path	»	• Strengthens patient centric digital programs, e.g. Transformation of Clinical Supply Chains • Decreases reaction time to study changes • Increases options for significant value-adds such as adherence programs, patient analytics, patient education

Design and Delivery Toolkit

❖ Deliverable:

- Prepare implementation toolkit to assist in regulatory engagement and facilitate voluntary adoption of e-Labeling

❖ Progress to Date:

- ✓ Chapters have been defined
- ✓ High level content per section completed
- ✓ Collected feedback via survey

❖ Next Step:

- Initial draft available for TransCelerate eLabel members May 2016

Health Authority Engagement



❖ Deliverable:

- Analyze global regulatory environment, create engagement strategy, and coordinate Health Authority engagements

❖ Progress to Date:

- ✓ Landscape analysis
- ✓ Health Authority Engagement Plan

❖ Next Steps

- Meet with at least 3 Health Authorities in 2016

Productivity Tools



❖ Deliverable:

- Support discussions with Health Authorities by providing solution options, capabilities, and benefits in an engaging way
- Aid in acceptance of future submissions that include e-Labels as a portion of the content
- Use POC as a mechanism to illustrate practical applications to regulators and verify stakeholder needs with patients and sites

❖ Progress to Date:

- ✓ Developed framework to analyze tool proposals
- ✓ Identified potential eLabeling technologies for development
- ✓ Implementation considerations

❖ Next Steps:

- Develop potential POC; not developing solution or standard

Potential E-label solution may need to solve for label application, comprehension and content management and update



A. What will be applied to packaging?



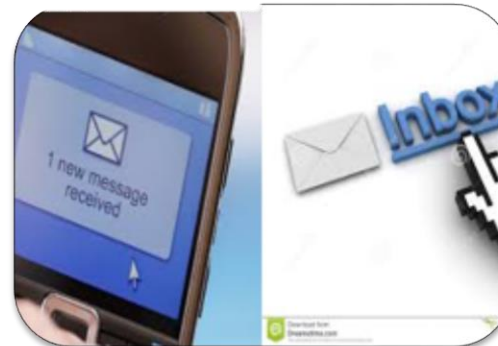
B. How will label be read and understood?



C. What label content will be embedded in packaging v/s information cloud?

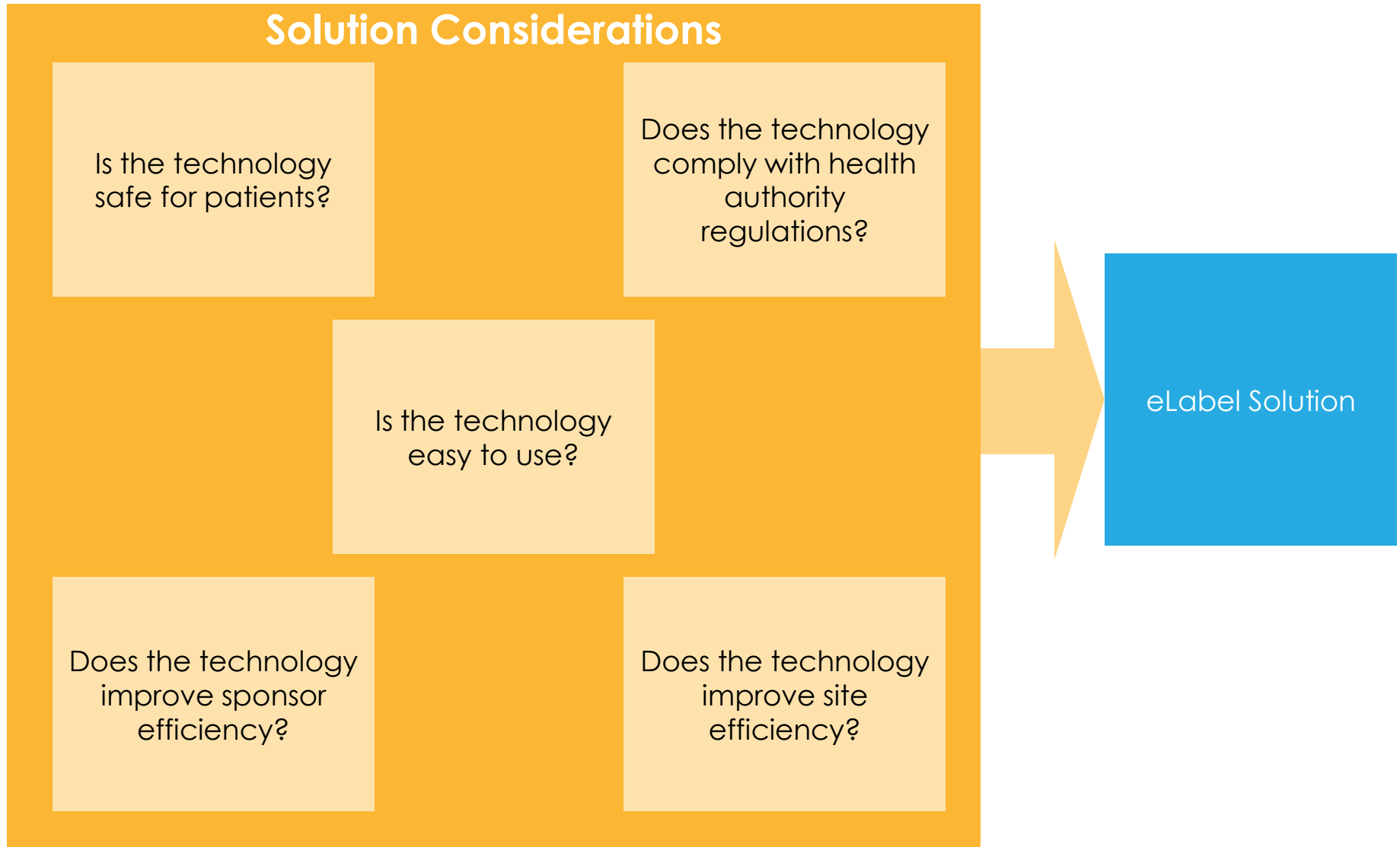


D. What method will be used to update and review label content?

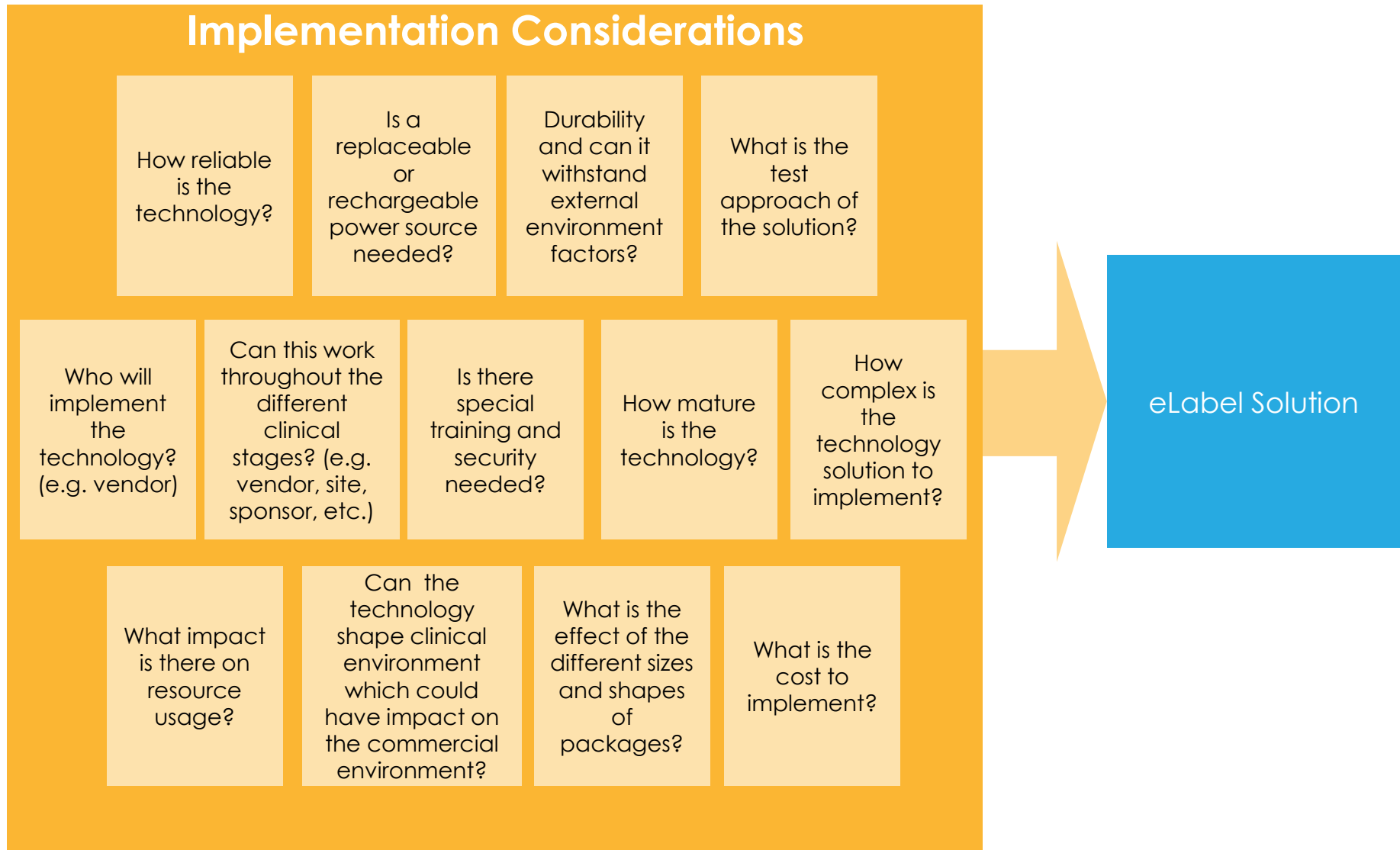


E. How will patient and sites be notified of label changes?

General Solution Considerations for all eLabel Technologies



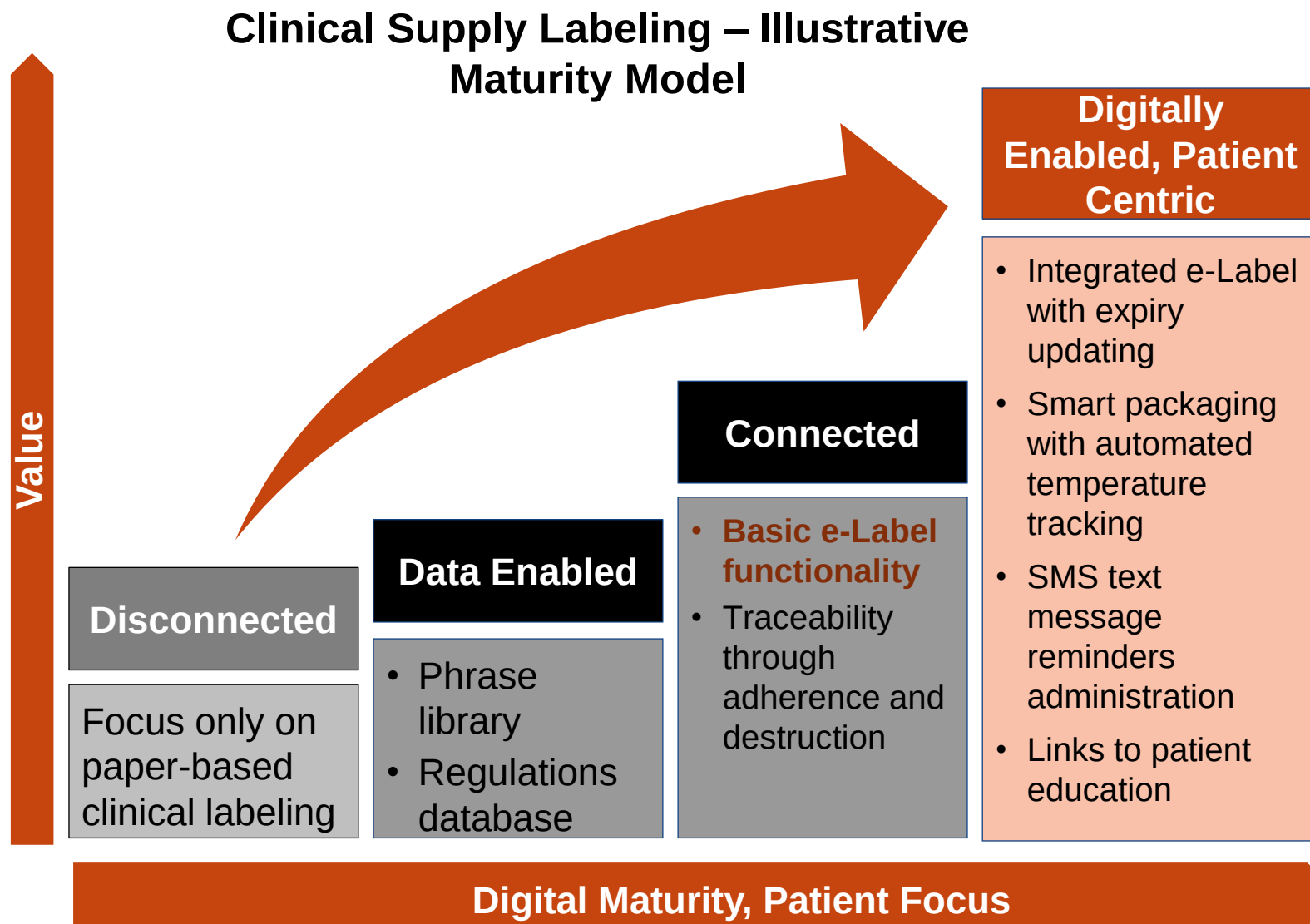
General Implementation Considerations for all eLabel Technologies



How to Engage

- If you're interested in participating on TransCelerate's e-Label initiative, and you are a member company, contact your leadership to get involved
- Even if your company is not participating, we welcome your feedback as we work to shape solutions for the industry. Visit TransCelerate's website for updates on the initiative

e-Labeling is Just the Beginning!



Thank you:

Any questions...?

