TransCelerate BIOPHARMA INC.

eLabels Business Case Template

Final: 15 Dec, 2017

eLabels Business Case Template Instructions

This business case template will help to facilitate collection of materials in support of developing an eLabels business case within a particular company. This Business Case Template, in addition to the Design and Delivery Toolkit are good starting points.

Typical Business Case content might include, among other things:

- Problem Statement
- Business Opportunity
- Stakeholder Identification
- Future State Efficiencies
- Quantitative and Qualitative Value/Benefits
- Risk Assessment
- Options Analysis

eLabels Opportunity Definition

Key facts (situation):
- New labelling technology has enabled functionality beyond regulatory requirements
- Greater geographic diversity in trials has increased demands on labelling
- Demand is increasing for more flexible, responsive labelling solutions
- Patients find low utility from current labels: Few booklets are opened, there is limited space for patient-centric information, and small font size impedes use

Unmet Need:
- Regulatory guidance concerning digital labelling
- Roll-out considerations or incorporating digital labels
- Vendors providing complete digital labelling solutions that satisfy stakeholder needs

Solution: Implement an electronic labeling solution for Investigational Medicinal Products (IMP) leading to enhanced patient safety/use, labeling cost efficiencies, accelerated trial timelines and greater efficiencies for sites.

Key Stakeholders

Internal: Quality Assurance (NA & EU focus), Clinical Supply, Clinical Ops, Distribution, Procurement, IT, Solution Vendors, Device Group, Packaging / Labelling, Leadership, Regulatory, Legal

External: CMOs, CROs, eLabel Vendors, HA, PAGs, SAGs, Patients, Sites, Sponsors, IRBs / Ethics, Customs, Logistic Service Providers, Ancillary Tech Companies, Integrated Voice, Booklet Manufacturers, Customs, Non-participating Companies

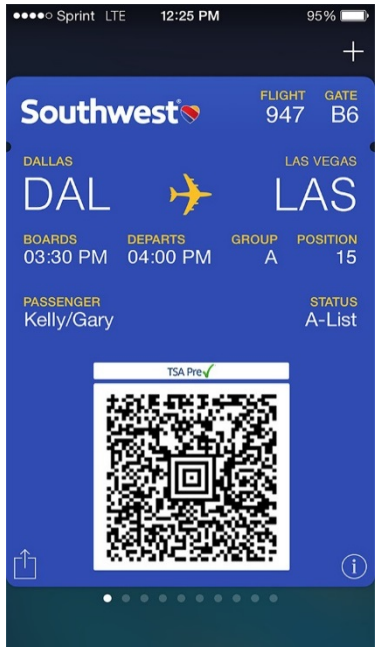
Benefit

Desired outcomes:
- Enhanced patient utility
- Faster access to up-to-date information
- Increased supply chain efficiency
- Ties into broader digital and innovation strategies

Criteria for quality / Value Drivers: 1) Increased access to information, 2) Increased ability to update information in real time, 3) Increased user functionality through notifications, learning modules, etc. , 4) Enhanced supply tracking capabilities, 5) Increased connectivity to patient and site, 6) Enhanced audit trail information capabilities for label changes, 7) Improved privacy and secure access, 8) Increased patient functionality an compliance

How is technology already mainstream and a critically important aspect of our lives?

Digital technology is leveraged to secure safe passage on air travel and to pay securely from your mobile device



eDiaries are leveraged extensively in Clinical trials to capture the patient experience

Wearables are already used in Clinical trials

eLabels Project Vision

The implementation of an eLabels solution can benefit the organizations primarily through an increase in production efficiencies, ease of use for sites, and an enhanced overall patient experience.

An eLabels solution can:

- Provide an innovative, user friendly, digital interface that enhances patient utility through improved readability, education, and medication compliance
- Provide patients with real-time updates to label content
- Enhance access to information about the Investigational product, preparation, dispensing, storage and use
- Enable a fully digital patient-centric clinical supply chain that increases speed and flexibility in IMP labeling and improves cost effectiveness due to reduced re-labeling*

*Benefit may be dependent on current Health Authority acceptance and evolution toward use of a universal label

eLabels Maturity Model

Clinical Supply Labeling – Illustrative Maturity Model

Value

Disconnected

- Focus only on paper-based clinical labeling

Link to Repository

- Phrase library
- Regulations database

Connected

- Foundation e-Label functionality
- Traceability through adherence and destruction

Digitally Enabled, Patient Centric

Digital Maturity, Patient Focus

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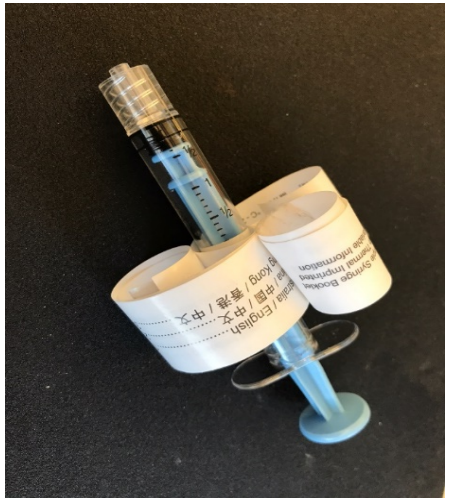
eLabels in Conjunction with a Universal Printed Label* Is An Efficient Alternative to Conventional Clinical Labeling

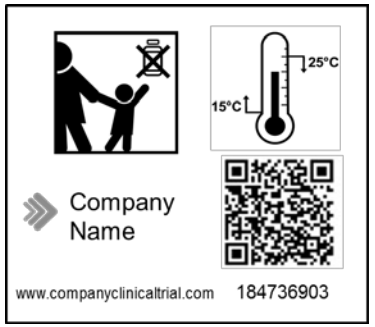
Current State

Booklet Label



Potential Future State

Universal Printed Label*



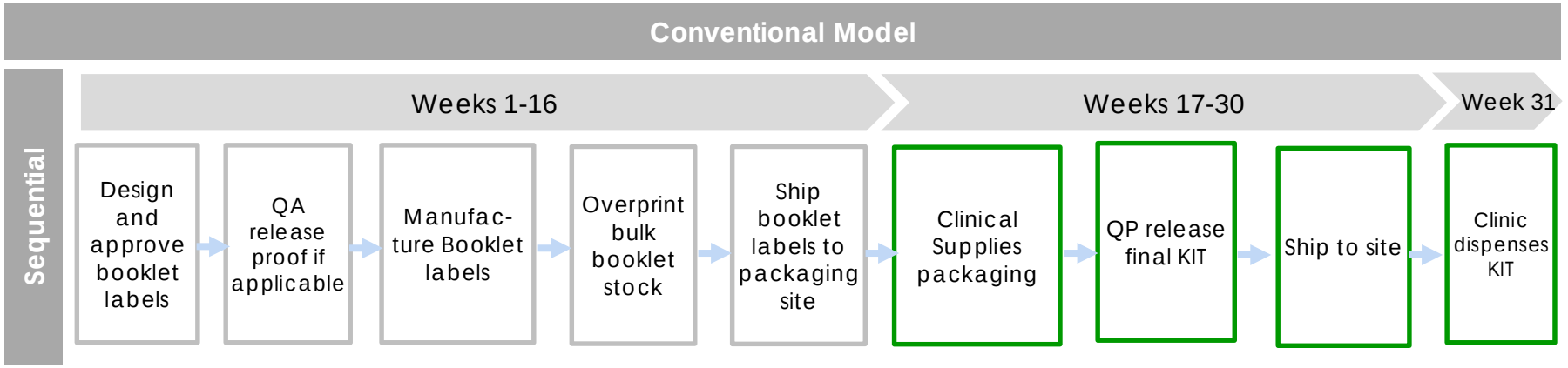
Minimal content on physical label to ensure patient safety and accurate dispensing

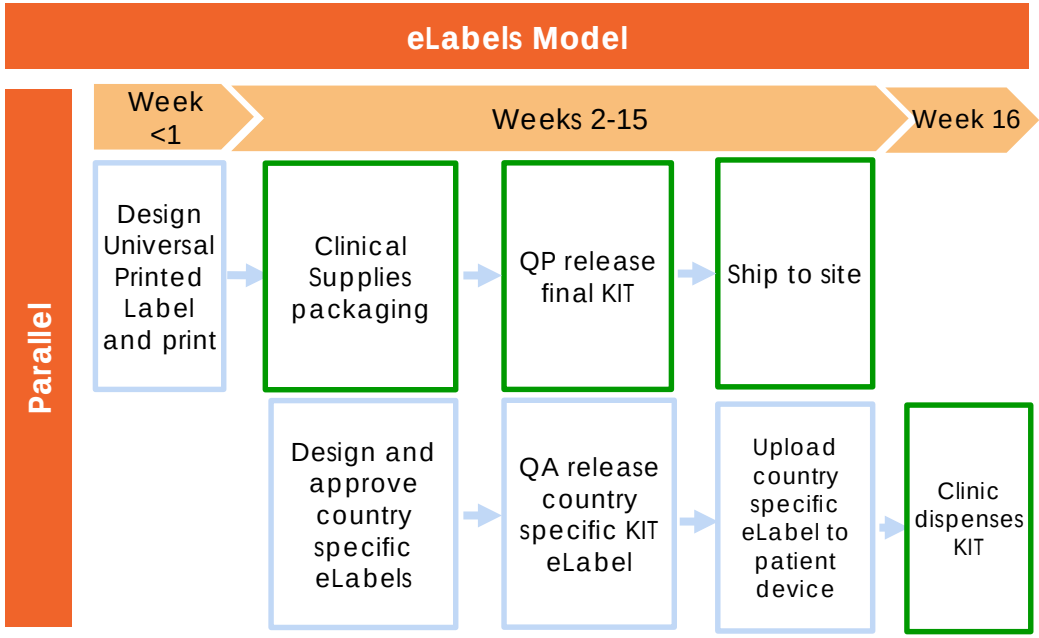
eLabel = "The Label"

Full regulatory-compliant label on electronic device

* Reducing the printed label content is not yet a viable option in all geographic locations

Illustrative Cycle Time Improvement: Conventional Model vs. eLabels Model *





Green boxes represent same activities between conventional and eLabel

*Not designed to scale; not all steps individually depicted

eLabels Address Common Pain Points and Benefits Stakeholders Across the Industry

Pain points and benefits may vary by sponsor

	Pain Points of Current Labeling	eLabels Benefits
Patients 	▪ Low usefulness of booklet labels: Few are opened, limited space and small fonts ▪ Booklet labels may impede functional use of a syringe or auto-injector ▪ Information on label is there to meet regulatory requirements, but may not include helpful information for the patient (eg, administration information)	▪ Increases efficiency in clinical development allowing for patients to receive medicines faster ▪ Increases patient safety ▪ Enhanced utility of clinical labels and potential for better compliance, e.g.: ➢ Dosing videos ➢ Supplements to communication ➢ Improved usability (e.g. larger font size)
Sites 	▪ Limited to no utility for sites except for the trial alias and kit number to aid in dispensing ▪ Limited or no space to write on the label	▪ Rapid access to up-to-date information ▪ Greater efficiencies in Labeling approaches ▪ Lays a future foundation for engaging with the patient about their medication
Health Authorities 	▪ New labeling technology has surpassed regulations ▪ Need to advance public health by accelerating innovation	▪ Decreases potential for deviations during extension re-labeling: e.g.: sterility, tamper evident seal, product mix-up, time out of environment ▪ Ensures latest information available for patients ▪ Ties into broader digital and innovation strategies
Sponsors 	▪ Paper labels are static, making updates lengthy and costly ▪ Multiple label groupings are needed to support global trials ▪ Long creation and approval times (multiple months) delay getting medicine to patients	▪ Increases operational efficiencies in creation of label ▪ Allows for additional pooling strategies which decreases waste ▪ Decreases reaction time to study changes ▪ Increases options for significant value-adds such as adherence programs, patient analytics, patient education

Potential Quantitative and Qualitative Value and Implementation Costs Considerations

Potential Quantitative Value Drivers

- Reduced cost of clinical drug labeling
- Reduced cost of re-printing clinical drug labels
- Reduction in destruction of drug at clinical sites
- Reduction in cycle time
- Increased pooling options potentially leading to less resupplies and decrease in waste
- Elimination of expiry date extension labeling process

Potential Qualitative Value Drivers

- Ties into broader digital and innovation strategies
- Enhanced utility of clinical labels and potential for better compliance
- Rapid access to up-to-date information
- Decreases reaction time to study changes
- Increased data integrity and data quality through use of source data throughout process
- Reduction in errors due to handling of kits

Potential Adoption and Implementation Costs

Depending on a company's current internal set up, there may be costs associated with:

- Technology, infrastructure, and systems
- Clinical development business process upgrade
- Validation, training, internal communications, and change management

Supportive Materials

Sample Options Template

	<Name of change> Incremental Change		<Name of change> Mid-level change		<Name of change> Most Transformational Change	
Description	<provide description of proposed change>		<provide description of proposed change>		<provide description of proposed change>	
Financial Impact	• $xM P&L in 2022 • $xM 5yr NPV		• $xM P&L in 2022 • $xM 5yr NPV		• $xM P&L in 2022 • ($xM) 5yr NPV	
VALUE						
Patient	○	• <provide description of impact of change on patient value >	◕	• <provide description of impact of change on patient value >	◕	• <provide description of impact of change on patient value >
Sites	◑	• <provide description of impact of change on site value >	●	• <provide description of impact of change on site value >	●	• <provide description of impact of change on site value >
Health Authorities	●	• <provide description of impact of change on health authority value >	○	• <provide description of impact of change on health authority value >	○	• <provide description of impact of change on health authority value >
Companies	◔	• <provide description of impact of change on company value >	◕	• <provide description of impact of change on company value >	◕	• <provide description of impact of change on company value >
RISK						
Business Risks	●	• <provide description of business risks>	◑	• <provide description of business risks>	○	• <provide description of business risks>
Implementation Risks	◔	• <provide description of implementation risks>	◑	• <provide description of implementation risks>	◕	• <provide description of implementation risks>

Legend
○ Low ◑ Medium ● High

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Insights on eLabels from Patients and Sites

Patients

ISPE Surveys

5,000+ previous clinical trial patients surveyed indicated:
(3,000+ US, 109 EU and 1,935 China)

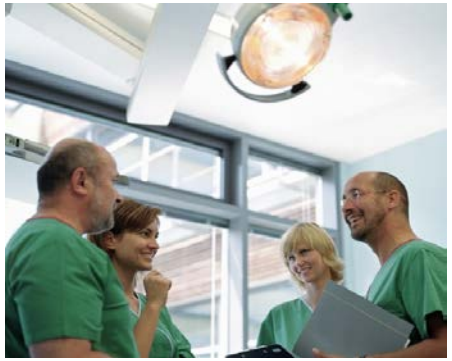
- Written and verbal instructions were valued most to ensure compliance
- The most helpful instructions via demonstration or verbally from site personnel where patients can ask questions
- Most preferred means to obtain information:
  - Email (EU and US)
  - Text message and postal mail (China)

[1]Patient Perceptions of Investigational Medicinal Products 2015 surveys in EU (and China), Esther Sadler-Williams 8th March 2016, Frankfurt

Sites

Over 65 site interviews in EU, US, Latin America and Japan[1] expressed support for eLabels and acknowledged the potential to:

- reduce human error and workload
- enhance readability of the label
- eliminate relabeling
- provide detailed dosing instructions
- track compliance
- provide notification to patient
- allow integration with patient diaries
- provide access to supportive videos



[2]TransCelerate Site Advisory Group and Lilly site interviews (SCRS)

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Critical Considerations for Sponsor Implementation

Items that must be addressed based upon technology chosen

- Patient Privacy
- Data Security
- Systems Validation
- Integration with Other Systems:
  - Interactive Response Technology (IRT)
  - Label Content Creation and Approval System(s)
  - Clinical Supply Demand/Planning and Distribution System(s)
  - Drug Accountability and Tracking System(s)
  - Sensor Systems (the Internet of Things)
  - Study/Site Portals
  - Enterprise Resource Planning (ERP) System(s)