eLabels: FAQ Table of Contents

- Benefits
- Design/Implementation
- Failure Mitigation, and/or Backup Plans
- Patient Access
- Patient Safety
- Privacy
- Regulatory
- Validation
Frequently Asked Question
How is eLabeling beneficial?

Response

• Increases efficiency in clinical development allowing for patients to receive medicines faster
• Enhanced utility of clinical labels and potential for better compliance (e.g., dosing videos, supplements to communication, improved usability via larger font sizes for example)
• Rapid access to up-to-date information
• Greater efficiencies in labeling approaches
• Lays a future foundation for:
  • engaging with the patient about their medication, including ensuring the latest information is available for patients
  • options for significant value-adds such as adherence programs, patient analytics, patient education
• Decreases potential for deviations during extension re-stickering (e.g., sterility, tamper-evident seal, product mix-up, time out of environment)
• Ties into broader digital and innovation strategies
• Allows for additional pooling strategies which decreases waste
• Decreases reaction time to study changes
• Increases options for significant value-adds

Resource Links

• The Near-Term Viability and Benefits of eLabels for Patients, Clinical Sites and Sponsors
• Pain Points vs. Benefits
• External eLabels website with additional tools and resources
**Frequently Asked Question**

What information will be on the pack for the pharmacist to pick packs from the shelf, particularly if there are multiple strengths/studies etc.?

**Response**

It will be the same process as today. Each container will be uniquely identified and have a kit number. Sponsors may also include trial alias and lot number.

**Resource Links**

- [eLabels design and implementation toolkit](#)
- [External eLabels website with additional tools and resources](#)
Frequently Asked Question
Will the eLabel QR code, Barcode, NFC or other technology only be on the outermost part of the patient kit?

Response
The eLabel QR code, barcode, NFC or other technology will be on the primary and secondary packaging (when separable).

Resource Links
- eLabels design and implementation toolkit
- External eLabels website with additional tools and resources
Frequently Asked Question
Can eLabels be implemented as supplementary to the existing paper label?

Response
Yes, sponsors may choose to implement both, dependent on local regulations.

Resource Links
- eLabels design and implementation toolkit
- External eLabels website with additional tools and resources
**Frequently Asked Question**
Which Health Authority has been most and least open to this concept?

**Response**
No Health Authority has had concerns regarding the technology. The questions that have been received are regarding the content left on the paper label and access to and use of the technology.

**Resource Links**
- [The Near-Term Viability and Benefits of eLabels for Patients, Clinical Sites and Sponsors](#)
- [External eLabels website with additional tools and resources](#)
Frequently Asked Question
Are there standard pictograms sponsors can use?

Response
Sponsors would have to use published pictograms (e.g., USP) or need to test the pictograms they were going to use. There are no standard pictograms used across industry.

Resource Links
- eLabels design and implementation toolkit
- Illustrative Cycle Time Improvement: Conventional Model vs. eLabels Model
- External eLabels website with additional tools and resources
Frequently Asked Question

What are the back-up plans to enable provision of full clinical label in the event of electronic failure, power loss, no connection, torn bar code, etc., to the investigator/patient/site/pharmacy?

Response

Each sponsor will need to confirm the specific back-up strategy to be used. The back-up strategy will not replace site/patient interaction, which is valued by patient, but will add to it.

If patients go home with the elabel, they will receive instruction at the site as to how to utilize an electronic backup (e.g., website) and/or will have an existing patient card with emergency contact information.

Sites/investigators will not need additional information, aside from what is on the remaining paper label.

Resource Links

• eLabels design and implementation toolkit
• External eLabels website with additional tools and resources
Frequently Asked Question
How will patients who do not have a phone or do not have a data plan be addressed?

Response
Sponsors may want to consider providing a device or covering the data used for the eLabel process.

Nearly nine in ten (89%) US adults over 50 own some type of mobile device and nearly three quarters of adults age 50-59 (73%) own a smartphone (AARP fact sheet).

Resource Links
- The Near-Term Viability and Benefits of eLabels for Patients, Clinical Sites and Sponsors
- External eLabels website with additional tools and resources
Frequently Asked Question
Will the patients read the electronic label if it is not paper?

Response
There is no training on reading the paper label. We know from various surveys and patient advisory groups that patients do not routinely open the paper label and read it. In the future there will be specific training at the site with the patient regarding their elabel and how to access it. It will be shown to them during that training to ensure the patient sees it at least once.

Resource Links
• eLabels design and implementation toolkit
• Pain Points vs. Benefits
• External eLabels website with additional tools and resources
Frequently Asked Question
What do you do when someone has a problem accessing the eLabel?

Response
It is important to keep in mind that neither the sites or the patients will go home without ensuring the patient is fully trained and can access the eLabel while at the site. Sites will be trained on how to mitigate access issues and how to train the patients. If there are still challenges, each sponsor will provide a back-up plan and the patient will still be able to contact their investigator if they have questions.

Resource Links
- Roles & Resources List Template accessed via tools and resources list
- External eLabels website with additional tools and resources
**Frequently Asked Question**
Will patient have the ability to print a physical label?

**Response**
Allowing patients to print labels may raise GMP concerns if the printed version of the e-label has not been verified (formatting, print quality, validation of printing).

**Resource Links**
- eLabels design and implementation toolkit
- External eLabels website with additional tools and resources

Release date: 2019-OCT-01
Frequently Asked Question
How will technology challenged (e.g., elderly) or visually challenged people use the eLabel?

Response
All patients will receive training which will be reinforced by site instruction. The eLabel could be enhanced by audio for those visually challenged. There may be some studies that due to the patient population where an eLabel may not be appropriate or where it will be necessary to have a care giver identified. It is the Sponsor’s responsibility to ensure specific enhancements of the eLabel are appropriate for their patients.

Resource Links
- eLabels design and implementation toolkit
- Pain Points vs. Benefits
- External eLabels website with additional tools and resources
Frequently Asked Question
How will the patient know if there is an update to label after they leave the clinic or pharmacy?

Response
This will be sponsor-specific and it also depends on the technology. The site will instruct the patient to check via the appropriate method. If updates are pushed, then a notification will appear for the patient with the update. If updates are pulled, then each time the label is accessed, a notification to check for an update will appear.

Resource Links
- eLabels design and implementation toolkit
- External eLabels website with additional tools and resources
**Frequently Asked Question**
How will eLabeling ensure patient safety?

**Response**
The processes to ensure patient safety will not change. The eLabel will not remove anything from what is currently communicated on the paper label. The eLabel will enhance patient safety, for example:

- Readability and access to detailed dosing information
- Additional features that could be added to the eLabel including recall notifications and adherence monitoring
- Automatic updates to dating which provides decreased potential to compromise product during extension ticking activities including potential breaches of sterility, no breaking tamper evidence seal, product mix-up, and time out of environment.

**Resource Links**
- The Near-Term Viability and Benefits of eLabels for Patients, Clinical Sites and Sponsors
- Pain Points vs. Benefits
- External eLabels website with additional tools and resources
Frequently Asked Question
For other individuals living in the same household and no access to a device, would it be clear and safe to them what the product is?

Response
Most clinical studies are blinded and the content of the IMP is not known. Information will still be on the label to aid in dispensing, traceability, and safety of the material.

Resource Links
- eLabels design and implementation toolkit
- External eLabels website with additional tools and resources
Frequently Asked Question
How is patient information protected?

Response
The system will be designed and validated to ensure that patient privacy will be maintained. There are many existing systems (e.g., Electronic Health Records) that have already been implemented that meet analogous requirements.

Resource Links
• eLabels design and implementation toolkit
• External eLabels website with additional tools and resources
Frequently Asked Question
How will Sponsors submit labels to health authority as part of protocol approval?

Response
This will remain consistent with the current process, proof will still need to be submitted to health authorities.

Resource Links
• eLabels design and implementation toolkit
• Illustrative Cycle Time Improvement: Conventional Model vs. eLabels Model
• External eLabels website with additional tools and resources
Frequently Asked Question
How will the app and technology be validated?

Response
The app and technology will be validated per a computer system specific to Health Authority requirements which are based upon the country of use. Specific validation plans will also be dependent upon the technology selected.

Resource Links
- eLabels design and implementation toolkit
- Illustrative Cycle Time Improvement: Conventional Model vs. eLabels Model
- External eLabels website with additional tools and resources