The Near-Term Viability and Benefits of eLabels for Patients, Clinical Sites, and Sponsors

Therapeutic Innovation
& Regulatory Science
2018, Vol. 52(5) 537-545
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DOI: 10.1177/2168479018765463
tirs.sagepub.com

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Abstract

Background: Current clinical trial labels are designed primarily to meet regulatory requirements. These labels have low patient and site utility, few are opened, and they have limited space and small fonts. As our world transitions from paper to electronic, an opportunity exists to provide patients with information about their investigational clinical trial product in a way that is more easily accessible, meets Health Authority requirements, and provides valuable additional information for the patient and caregiver. **Methods:** A TransCelerate initiative was launched to understand the current regulatory and technology landscape for the potential use an electronic label (eLabel) for investigational medicinal products (IMPs). Concepts and an example proof of concept were developed intended to show the “art of the possible” for a foundational eLabel and a “universal printed label.” In addition, possible patient-centric enhancements were captured in the eLabel proof of concept. These concepts were shared with Health Authorities as well as patient and site advisory groups to gather feedback and subsequently enhance the concepts. **Results:** Feedback indicated that the concept of an eLabel provides value and concepts should continue to be pursued. While the Health Authorities engaged with did not express issues with the use of an eLabel per se, the reduction in the content on the paper label is not possible in some geographic locations due to existing regulations. **Conclusions:** There is nothing that prevents transmitting the label electronically in conjunction with current conventional labeling. While there are still some regulatory barriers that need to be addressed for reducing what is on the paper label, advancement toward a more patient-centric approach benefits stakeholders and will enable a fully connected patient-centric experience. The industry must start now to build the foundation

Keywords

TransCelerate, booklet label, clinical trial label, eLabels, investigational medicinal product

Introduction

Everyone gets smarter because of technology . . . and the empowerment of people is the secret to technological progress.

(Eric Schmidt, Executive Chairman for Google USA at the “In Tech We Trust and The Future of the Digital Economy at Davos,” 2015).

Technology is used every day in the world around us. Banking is an industry that employs a great deal of technology. In fact, the automated teller machine (ATM) is the first “Internet of Things” (IoT) object that became commonplace. Booking an airline ticket and acquiring a boarding pass no longer require any human interaction. Medical records are now digital and can be accessed electronically. In these very high-risk areas, security and privacy have been addressed.

Technology can also be harnessed to improve the utility of the investigational clinical trial product (hereafter, referred to

as investigational medicinal product [IMP]) label. The static or printed IMP label typically has limited text area for instructions (eg, on a vial, syringe, etc) and may have up to 19 different regulatory required elements (Table 1). This situation tends to result in font sizes that are difficult to read and search. The resulting label meets regulatory requirements but is not patient

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Submitted 5-Dec-2017; accepted 23-Feb-2018

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Table 1. Representative Region-Specific Labeling Requirements.^a

Minimum labeling criteria	US		Japan		Canada		EU + Annex 13		India		EU Annex VI	
	2°	1°	2°	1°	2°	1°	2°	1°	2°	1°	2°	1°
Contact name							R	R	R	R	R	R
Contact address							R				R	
Contact telephone							R				R	
Name: shipper, importer, manufacturer									R	R		
Address: shipper, importer, manufacturer									R	R		
Drug name			R	R	R	R	R	R	R	R	R	R
Strength / potency / dosage							R	R	R	R	R	R
Dosage form							R	R	R	R	R	R
Route of administration							R	R	R	R	R	R
Quantity of dosage units							R	R	R	R	R	R
Batch/lot	R	R	R	R	R	R	R	R	R	R	R	R
Trial reference code					R	R	R	R	R	R	R	R
Subject number							R	R	R	R	R	R
Investigator name / number							R		R	R	R	
Directions for use							R				R	
“Clinical trial use” phrase	R	R	R	R	R	R	R		R	R	R	
Storage conditions			R		R	R	R		R	R	R	
Expiry date / period of use					R	R	R		R	R	R	R
“Keep out of reach of children”							R		R	R	R	
Handling / special precautions			R	R	R	R			R	R		
Manufacture date									R	R		
Country-specific language			R	R	R	R	R	R	R	R	R	R

Abbreviations: R, required; 1°, label on the primary or immediate packaging; 2°, label on secondary or outer packaging.

^aThis table is provided for informational purposes and is not intended to provide legal advice. Each company is responsible for determining compliance with specific laws, regulations, and guidances.

friendly. Leveraging technology for an IMP label by using electronic labels (eLabels) can provide the clinical trial patient with all the knowledge he/she needs by enhancing the utility of the clinical label and thus potentially improving compliance and safety.

The development and use of eLabels fit into a broader trend toward utilizing digital and innovative technology in clinical trials. Clinical trials are increasing their utilization of technology to aid in the patient experience as well as to capture information more efficiently. Some examples include the electronic diary (eDiary), electronic data capture (EDC), wearables, and electronic informed consent (eConsent). Many Health Authorities have also been encouraging utilization of technology to improve patient health (Table 2). Use of eLabels will help ensure that the patient has the most current information and may decrease deviations during extension relabeling (to update the expiry date). Transmitting the label information electronically is an achievable goal that will benefit the patient, site, Health Authorities, and sponsors. For the purposes of this publication, definitions of specific terms are provided in Appendix A.

Current Situation

The IMP label provides patients and sites with critical information such as dosing instructions, storage conditions, and

Table 2. Examples of Health Authorities' Initiatives for Technology Innovation in Clinical Trials.

Health Authority	Innovation
US FDA	Using technologies and innovative methods to conduct Food and Drug Administration–regulated clinical investigation of investigational drugs Electronic distribution of prescribing information for human prescription drugs
Belgium Germany BfArM	Electronic leaflet for medical products Medical apps for the commercial space
AEMPS	Investing in connected health and remote health applications for physicians to interface with homebound patients
Korea MFDS	Allowing use of a quick response (QR) code on commercial labeling to electronically augment the paper label

Abbreviations: AEMPS, Spanish Agency of Medicines and Medical Devices; BfArM, Federal Institute for Drugs and Medical Devices; MFDS, Ministry of Food and Drug Safety.

drug expiry. Each label also needs to include country-specific labeling requirements in the local language of the participating country. Table 1 describes the different elements required by representative Health Authorities around the world; it is not

Figure 1. Pros and cons of booklet labels for the sponsor.

intended to be an exhaustive list of all requirements in all countries. Managing these country-specific requirements can be complex and challenging enough for the sponsor, but the patients and sites must live with the consequences of the label's font size being inversely proportional to the amount of required text, which can lead to font sizes as small as 6 points being used on some labels.

Currently, IMP labels are commonly grouped into a booklet label that allows the IMP to be distributed in multiple countries. Each page of the booklet label contains the label requirements designated by the specific country's Health Authority and is translated into the country-specified language. While the transition to booklet labels has achieved many upsides, it has also caused challenges (Figure 1).

In addition, patients and sites have expressed dissatisfaction with the booklet label. TransCelerate sponsored patient and site advisory groups to collect information on conventional labeling practices and electronic options. Comments received from the patients during the advisory group meetings included

- "Font is too small."
- "Doesn't contain the information I need."
- Caregiver: "Labelled bottles with a magic marker to know when to take pills from different bottles."

The site feedback included

- "Difficult to locate and select correct container based on Kit ID."
- "We'd never dispense something like this in a retail setting."
- "Patients rip it off or don't even open it."

An International Society of Pharmaceutical Engineering (ISPE) global survey composed of over 5000 patients found that the most preferred method of obtaining information was verbal followed by an electronic form.¹ Email was favored in the EU and US; in China, respondents chose text messaging as the preferred route.¹ A global survey conducted by TransCelerate and

the Center for Information and Study on Clinical Research Participation (CISCRP) with over 3000 patients confirmed the ISPE survey findings by noting that the most preferred method to receive information on clinical trial medicine is from the health care provider. The second and third most preferred methods were electronic (online and by email, respectively).

Health Authorities are also interested in ways to leverage technology and innovative methods to support the growing challenges of engaging with patients in more effective ways and improving patient safety (Table 2).

In addition, today's clinical trials are becoming more complex and costly. Increasing cost of material for innovative IMPs are contributing to the soaring costs of research and development (R&D). Finding ways to be more efficient and cost effective with IMP materials is an opportunity to address these costs. Use of eLabels provides an opportunity to expedite distribution of limited IMP more quickly by minimizing inventory loss due to relabeling and reallocation. More patients can be served with the same limited inventory of IMP and comparator.

Future State

The advancement of technology brings opportunities to an industry traditionally constrained with using physical labels for IMPs. The concept of a digitally supported platform was developed to enhance clinical trials by leveraging eLabels.

The foundational eLabels concept is designed to provide regulatory label requirements, delivered in the country-specific language, via a user-friendly, electronic device. The label on the electronic device leverages a simplified, language-agnostic, printed label on the physical packaging. These electronic devices can be a smartphone, tablet, personal computer (PC), or electronic display on the container (smartphone example in Figure 2). Electronic text size can be modified to enable readability. Information such as investigator contact information and site details can be present when it is dispensed, eliminating the need to write on the kit. The eLabel is intended to support an efficient, patient-centric, comprehensive, and integrated approach for providing regulatory compliant IMP

Figure 2. Example eLabels concept.

information to sites and patients. However, it should be noted that in some countries, Health Authorities may require that eLabels are used only in combination with traditional paper labels bearing the country-specific required text.

Additional features, such as the following, can be added to improve the benefits to patients and sites:

- Access to videos showing how to use the IMP
- Updates to the expiry date including notification of the update to the patient
- Changes in dosing instructions with a patient notification that a patient must acknowledge receiving
- Reminders to the patient if a dose is not taken at the correct time
- Log (diary) to track IMP use
- Ability to track the temperature of the pack and provide patient notification not to use the product if the temperature deviates from the acceptable range
- Ability to apply accessibility options (eg, audible functionality for the visually impaired)

Figure 3. Container and example universal printed label.

The actual IMP package or container would display a simplified, language-agnostic, printed label, known as the universal printed label that contains minimal information (eg, pictograms and numbers) not requiring translation into any specific language. The printed label would include the minimal items needed for identification, safety, and dispensing (including traceability) of the IMP while directing the user to the eLabel. The pictograms would be mirrored on the eLabel to maintain continuity and patient understanding. The printed label can be laser etched directly on the container or printed on a single-panel label. Access to the eLabel can utilize any of the following:

- Electronic chips (radio-frequency identification [RFID], near field communication [NFC], and Bluetooth)
- Interactive displays (light-emitting diode [LED] and electronic ink)
- Barcodes
- Interactive buttons for audio or videos

An example of a universal printed label is shown in Figure 3.

The use of the universal label is not accepted by all Health Authorities and the traditional paper label may need to be used with the electronic version.

While change is often slow in a heavily regulated industry, technology has evolved more rapidly than the regulations. Because of the difference in the rate of change, the evolution of the clinical trial label process has been limited to date. However, the use of technology offers exciting potential in this area. Figure 4 provides an illustrative maturity model of the evolution of the label as technology is introduced into the clinical trial labels process.

- **Disconnected:** Some company processes require every label, translation, and all regulatory requirements to be approved by the local affiliate or contract research organization (CRO). This slow and inefficient process requires a long lead time that can delay the start of a study, thus affecting the patient. Additionally, variability

Figure 4. The evolution of labeling.

in the local affiliate/CRO's knowledge and experience had the potential to introduce inconsistencies or cause label revisions. Any modification to a label that had been approved, printed, and/or applied could result in additional delays in delivering the IMP to the patient.

- **Link to Repository:** Additional efficiency can be gained by developing preapproved phrase libraries and regulatory database repositories to address these issues. Implementing these repositories can decrease lead time for label creation, provide consistency in label content, and decrease label approval time.
- **Connected:** The next phase of evolution is an eLabel that can be developed in parallel with other clinical supply activities.

eLabels have the potential to offer multiple benefits for patients, sites, and Health Authorities as well as sponsors. Each of these stakeholders was consulted during the development of the TransCelerate eLabels concepts through surveys, advisory groups, simulations, and a pilot. While some Health Authorities have concerns about the lack of content on the universal printed label, the eLabels concept was generally well received. In fact, as stated previously, patients surveyed chose electronic means as their second and third most preferred means of obtaining information, following receiving information from their health care professional.

When shown an example eLabels proof of concept (Figure 2), patients in the TransCelerate patient advisory group said the

information was presented in a “clear and easy to read format that would make them more likely to read the information.” The eLabels functions were a “valued resource” in a pilot conducted in Belgium.² Having access to additional information beyond regulatory requirements and communicating real-time updates can be important in possibly leading to better compliance. Additional information could include add-on functionality such as instructional videos and notifications to assist with adherence. Just the basic functionality of having improved usability, such as a larger font size and a search feature, could encourage patients to read the label. As one patient in the TransCelerate Patient Advisory Group stated, “I don’t read the leaflet because, me, when I open them, the print is so tiny, it’s the tiny little writing.” Furthermore, the combination of including these enhancements could greatly increase patient safety because patients would be able to identify the product more easily and ensure that the information on their medication is the most up-to-date.

Sites participating in TransCelerate’s Site Advisory Group also expressed support for eLabels, noting that it could enhance readability and efficiencies in labeling approaches by reducing manual entry, relabeling, and extra handling. As with patients, sites would receive rapid access to up-to-date information that would re-enforce patient safety and ensure accurate dispensing. Additionally, the sites could be provided with training materials to educate patients. Providing training has the potential to foster greater engagement between patients and site personnel. Furthermore, potentially, an eLabel could reduce human error

Figure 5. Illustrative cycle time improvement: comparison of processes for conventional labels and eLabels.

while logging in material, relabeling, and doing manual accountability activities. This would allow site personnel to focus more time on the patients.

As with patients and sites, Health Authorities are interested in technologies that will provide greater patient safety, compliance, avoidance of operational errors, and alignment with their broader digital and innovation strategies (Table 2). By utilizing eLabels, the potential for deviations due to paper relabeling operations will be eliminated. This includes deviations caused by sterility breaches, tamper-evident seal removal, product mixup, and temperature excursions. Furthermore, any IMP changes that would impact the label content could be communicated rapidly and directly to the patient via the eLabel to further support patient safety and compliance.

As drug development costs and trial complexity increase, eLabels also offer advantages for sponsors such as operational efficiencies in label creation that shorten timelines, allowing patients to receive their medications faster (Figure 5). eLabels also allow for additional pooling strategies that decrease waste and potential stock-outs. Less waste and shortened lead times translate into considerable cost savings by reducing or eliminating the need for printing and ordering booklets. Sponsors also benefit from the flexibility to revise the label in real time (eg, the addition of a new country, an update to stability information, or update to a country's regulations). Furthermore, eLabels could provide

additional functionality for sponsors, thereby increasing options in monitoring patient adherence.

Technology Adoption Challenges

One of the greatest challenges to rapidly progressing innovative drug development is patient recruitment into the clinical trials. Strict restrictions on patient inclusion criteria may already lead to slow recruitment, and any further obstacles to this process are certainly not welcome. Therefore, one must ask, would the adoption of an eLabels solution help or hinder this process?

In the developed world, there is no doubt that digital media is advancing and being adopted by the general population at an incredibly rapid pace. However, the following concerns must be addressed:

- What does the global landscape look like? Is there sufficient WiFi/Internet connectivity and access to the necessary hardware?
- Do all age groups embrace technology equally?
- Will the patient lose interest in the eLabel and associated additional features?
- How will the technology work for individuals with physical limitations (eg, visual impairment)?

Global Connectivity

An eLabels solution may simply not be practical in every corner of the globe, particularly where access to Internet/cellular/WiFi service is not possible. However, not surprisingly, in most of Western Europe and North America, Internet penetration has reached 84% and 88%, respectively.³

A recent publication by Hootsuite reviewed Internet, social media, and mobile data from around the world.³ The data came from various sources, including public and private companies, market research firms, government agencies, nongovernment organizations (NGOs), and private individuals. The authors found that more than half of the world's population uses the Internet (ie, more than 3.75 billion people), with a year-over-year increase of 8%. Furthermore, mobile connectivity continues to grow as well. Nearly two-thirds of the world's population across all age groups now uses a mobile phone, and with 55% of all active connections now coming from smartphones, it is likely that more than half of the world's population now uses this technology.

But having access to a smart phone or the Internet does not necessarily mean comfort in using the technology. A recently published report explored the relationship of UK consumers, from teenagers to pensioners, with the latest technologies.⁴ Most consumers thought technology had a positive impact on their day-to-day lives. Also, there was strong recognition that future technologies will play an important role in later life, particularly in terms of enabling greater independence in old age.

A recent report stated that "A common misconception is that people over 65 will reject technology and refuse to integrate it into their daily lives."⁵ Older adults are adopting new technologies into their way of life more than ever. Indeed, more than half of older adults are active online. A 2016 Pew Research Center report found that 64% of older adults (age ≥ 65 years) use the Internet, up from 14% in 2000.⁶ A 2016 AARP (American Association of Retired Persons) survey found that nearly 9 in 10 (89%) adults over 50 years old own some type of mobile device and nearly three-quarters of adults aged 50 to 59 years (73%) own a smartphone.⁷ These findings indicate that older adults are willing to learn and use new tools if given the right training.

It is not surprising that adults aged 65 years and older find it more difficult to master the latest technologies initially compared with younger people. Younger consumers grew up with the technology and adopt it very easily. Working people have a level of support through their work or colleagues. However, this type of support does not exist on a daily basis for older adults who might be retired from work, live alone, and not have access to tech-savvy children or grandchildren. Furthermore, older adults also experience declines in perceptual, motor, and cognitive function. However, these challenges can be overcome. It is important to ensure that effective support mechanisms are in place to help consumers of all ages.

Gamification

Assuming patients do adopt the technology, keeping their interest in it and maintaining the benefits offered by it is the next challenge. While this may not be critical for the core eLabels solution, it will be for some of the many additional features that the platform may offer. A study by apps analytics provider, Flurry, showed that half of all apps lost half of their peak users within 3 months.⁸ It is therefore imperative that sponsors invest in various techniques to ensure continued patient engagement. Many of the more successful medical mobile apps demonstrating longevity achieved it through gamification. By introducing gaming dynamics into these apps, patients are incentivized with points or tokens, maintaining their engagement by appealing to their natural human desires for rewards.

Expanding Access to Medicines

It is quite possible that eLabels, and the additional functionality that they offer, may increase the potential patient populations for clinical trials, increase patient diversity, and provide the critical access to IMPs that most people already expect.

For example, eLabels could address the currently unmet needs of the visually impaired or blind by accommodating increased font size and/or using audio. According to the Royal National Institute for the Blind, 2 million people in the United Kingdom live with sight loss (1 in 30); of these, 360,000 are registered as blind or partially sighted.⁹

eLabels in the Clinical Trial Environment

Challenges exist, but adoption of eLabels is no different than general adoption of other technologies including online banking or electronic medical records. Privacy, security, and availability of the infrastructure and devices as well as backup processes are valid concerns that need to be addressed systematically and mitigated according to the method of eLabels technology deployed. Not all eLabels solutions are the same; some do not require constant connectivity or WiFi. Some may need to provide devices to sites and patients, while others may have them use their own devices. Consequently, different approaches may be necessary to meet different challenges.

Furthermore, unlike other technologies outside of the clinical trial setting that are often dropped onto the general population without any consideration of access to hardware, connectivity, or backups, and that may be used by technology-averse subpopulations, the clinical setting is very different. It is a more contained environment. Patients and investigators have 1-on-1 interactions. Hardware and connectivity issues can be discussed and addressed. Training can be provided, backup plans discussed, and competency assessed, and patients in clinical trials always know whom to contact if they have any questions.

TransCelerate Tools for the Development and Implementation of eLabels and Universal Printed Label Concepts

Since mid-2015, the TransCelerate eLabels project has been working to develop a toolkit to help develop and implement an eLabels solution that meets the needs of sponsor companies and the infrastructure and requirements they will encounter in the eLabels environment.

The TransCelerate toolkit contains a technology assessment for examining various means to transmit a label electronically. A visual representation of an eLabel based on site and patient feedback is provided. Additional site and patient feedback contained in the toolkit can aid in the development of user stories that can be utilized to develop the solution. Health authority strategy and engagement feedback is outlined for consideration on using the universal label in conjunction with the eLabel.

The toolkit has been released and is available for free on the TransCelerate website under the eLabels workstream initiative at <http://www.transceleratebiopharmainc.com/initiatives/eLabels/>. It not only helps the pharmaceutical industry but also aids technology vendors in developing solutions that meet the needs of sponsors, sites, and patients.

Conclusion

Change takes effort and time, but when there are clearly articulated benefits for the patients, clinical sites, Health Authorities, and innovators, change is needed. Obstacles can be overcome as we approach them with the whole community in mind and a culture of quality and safety. eLabels are not a futuristic dream. Its time has come as the pharmaceutical industry strives to focus on the patients. There is nothing that prevents transmitting the label electronically in conjunction with current conventional labeling. However, additional benefits regarding speed of getting IMP products to our patients and development cost reductions occur when the eLabel is paired with the universal label. The uptake of the universal label by Health Authorities will not occur simultaneously; therefore, the solution may not initially look globally uniform.

The industry must start now to build the foundation to enable a fully connected, patient-centric experience. Patients are waiting on us.

Appendix A

Glossary

Add-on functionality: Innovative additional features that improve patient and site experience and enhance data integrity (ie, dosing videos, sensors, etc).

Device: Electronic platform containing information.

eDiary: An electronic diary used by the patient to record a self-assessed medical experience in real time, such as migraines or quality-of-life restrictions, while in a clinical trial.

eConsent: For patients participating in a clinical trial, an electronic consent captures insight into patients' understanding while increasing regulatory compliance and reducing quality risks.

Foundational eLabel: Provides regulatory-complaint label via a user-friendly, electronic equivalent with a simplified printed label.

Just-in-time: Local regulatory, country, and study-specific requirements are printed on a label, per shipping request, and then applied to the final preassembled kit prior to shipment.

On-demand: Local regulatory and study-specific requirements are printed on a label, on demand, at the point of assembly and applied to create a unique kit.

Pictogram: Images or symbols that convey medication instructions, precautions, and/or warnings to users.

Universal Label: Printed label that contains limited, language-independent information (eg, numbers and pictograms) and directs users to an electronic label (eLabel).

Acknowledgments

All authors were involved in the writing and editing of the article. As applicable, licenses for all figures have been purchased.

The authors gratefully acknowledge the support of TransCelerate BioPharma Inc, and the TransCelerate eLabels Initiative team. TransCelerate BioPharma Inc is a nonprofit organization dedicated to improving the health of people around the world by accelerating and simplifying the research and development (R&D) of innovative new therapies. The organization's mission is to collaborate across the global biopharmaceutical R&D community to identify, prioritize, design, and facilitate implementation of solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.

Declaration of Conflicting Interests

No potential conflicts were declared.

Funding

No financial support of the research, authorship, and/or publication of this article was declared.

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