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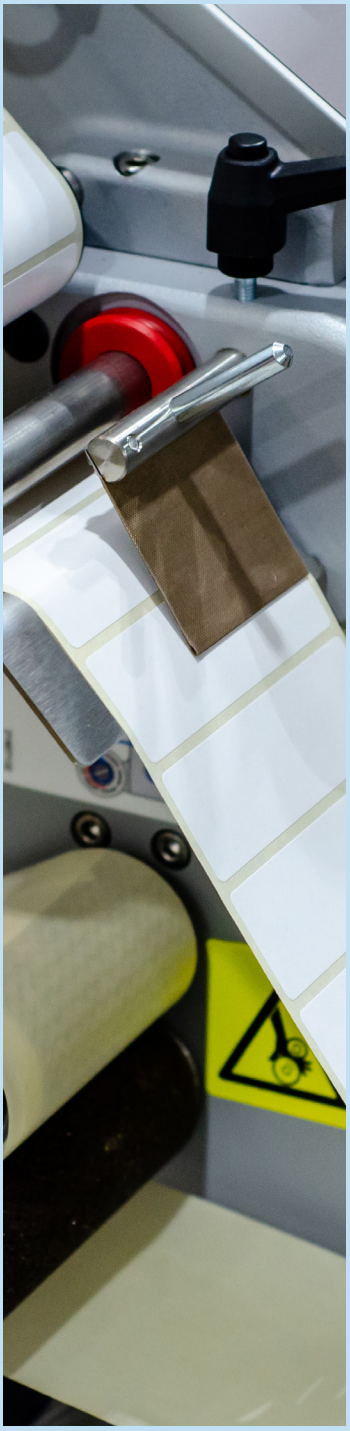

UNLOCKING CLINICAL LABELLING: CHALLENGES, SOLUTIONS, AND THE INFOSYS ADVANTAGE

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Introduction

Clinical labelling is a vital component in the development of medical products during clinical trials. It refers to the process of assigning specific information to an investigational drug, other medicinal products, or device throughout its research journey. They include information such as Mode/route of drug administration, Lot or batch number, Dosage, concentration, and strength, Expiration date, Storage requirements, etc. This information serves multiple purposes for patient safety, regulatory compliance, and effective communication

Clinical labelling must meet regulatory compliance and stringent requirements set forth by regulatory agencies such as Food and Drug Administration (FDA) and European Medicines Agency (EMA). Investigational Medicinal Products must be labeled in accordance with local regulations of each country, labels must be in local language in most countries and each study must have a clinical trial label for each drug included in the study..

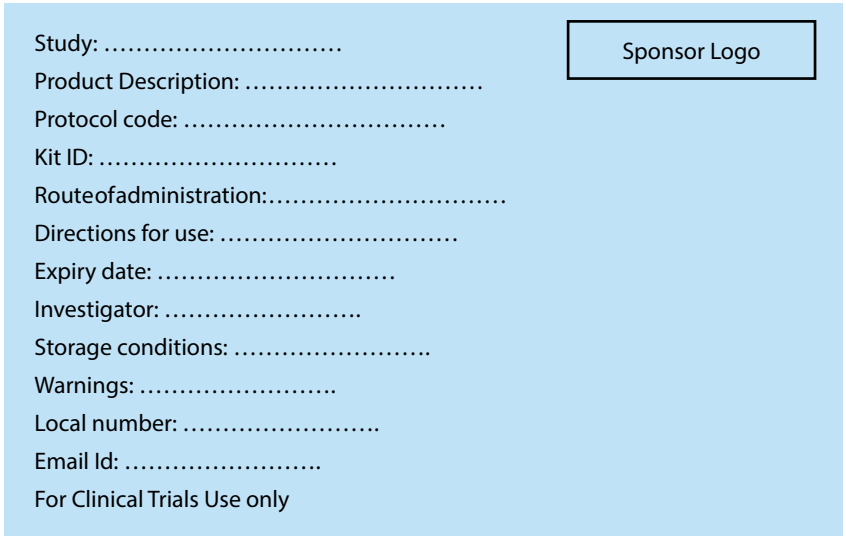


Figure 1: Single Panel Clinical Label

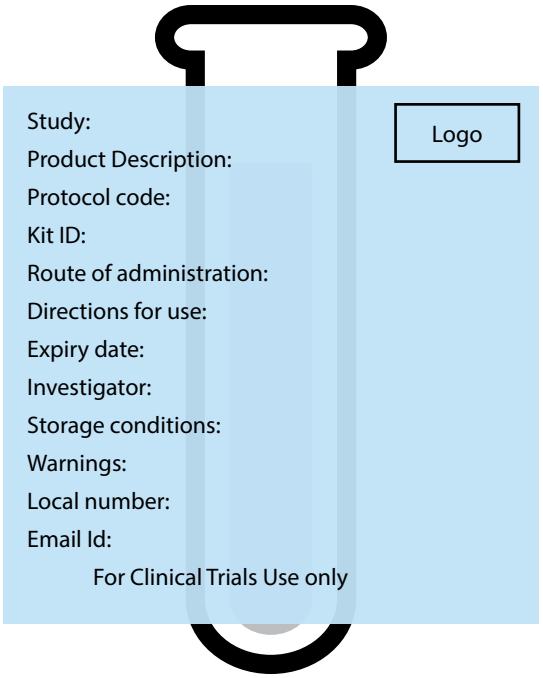


Figure 2: Vial Label

Above are the two typical clinical labels which are used extensively during the trials.

Note: These are for representation purpose and actual labels might vary according to each company and country guidelines.

Types of labels:

- Primary Packaging labelling: It comes in direct contact with the product itself. In the case of pharmaceuticals, primary packaging usually takes the shape of ampoules, vials, containers, strip package, blister packaging, syringe, dosing doppler, sachet packaging, etc.
- Secondary Packaging labelling: It applies to outer packaging on the drug case and on the box, crates, or cartons. Its purpose is to facilitate logistics and storage.
- Booklet labelling: They provide essential information bout an investigational drug or device in multiple languages, allowing for flexible distribution and use across different international locations.
  Furthermore, label types can be Blinded labels, Slope cut labels, Tube labels, and Treatment Unblinded Reports.

Labelling process is critical and hence is often fraught with challenges that can impact the integrity of the clinical trial and patient safety. In this article, we have highlighted the key challenges faced and discussed potential strategies to overcome them.

What challenges are organizations facing in clinical labelling?

- Supply Chain Integration

  Clinical packaging and labelling are integral components of the clinical trial supply chain. Effective integration of these processes with other supply chain activities, such as manufacturing, distribution, and inventory management, is essential for ensuring the timely and accurate delivery of investigational drugs to clinical sites.

- Geo-political scenario with complex regulatory landscape Clinical trials are subject to stringent regulatory requirements, particularly in terms of packaging and labelling. These regulations, often varying across different countries and regions, mandate specific information to be included on labels, such as drug identification, dosage instructions, warnings, and storage conditions. Navigating this complex regulatory landscape can be challenging for pharmaceutical companies, especially when conducting trials in multiple regions.

- Multilingual Labelling Requirements Clinical trials often span multiple countries with diverse linguistic backgrounds, necessitating multilingual labelling to ensure patient comprehension and safety. Accurate translation and adaptation of labelling content to different languages and cultural contexts is crucial. Translations for Left-Right and Right-Left is different, and system must be capable to manage all such translations. This process requires meticulous coordination and ample resources, as inconsistencies in translations can lead to medication errors and adverse events.

- Flexibility and Adaptability Clinical trials are dynamic processes, often undergoing protocol changes and amendments. Packaging and labelling must adapt to these changes quickly and efficiently to maintain compliance and ensure patient safety. This flexibility is particularly critical when dealing with last-minute protocol changes or unexpected events during the trial.

- Data Management and Traceability Clinical packaging and labelling involve overseeing vast amounts of data, including product information, patient details, and tracking information. Ensuring the accuracy, consistency, and accessibility of this data is paramount for maintaining regulatory compliance and traceability. This challenge is amplified for companies with extensive product portfolios and global clinical trials.

What innovations are happening that can help them solve their challenges?

- Early Planning and Collaboration:

  Proactive planning and collaboration between stakeholders, including sponsors, contract packaging organizations, and regulatory experts, can help anticipate and address potential challenges early on.

- Technology Adoption:

  Leveraging technology solutions, such as labelling software, data management systems, and track-and-trace technologies, can streamline processes, enhance data accuracy, and improve traceability.

- E-Label:

  It refers to the electronic version of the traditional paper labels with information about an investigational medicinal product (IMP) used in clinical trials. Certain regulatory hurdles the adoption of e-labels but regions like Singapore have begun implementing it.

- JIT (Just in Time) Labelling:

  Just-in-time labelling (JTL) is a process where products are labeled just before distribution rather than all at once. Such a postponement strategy, can greatly reduce or eliminate the need to relabel kits and allow for greater flexibility, which cuts down on waste.

- Standardization and Harmonization:

  Promoting standardization and harmonization of labelling requirements across different regions can reduce complexity and facilitate compliance.

- Flexible Packaging Solutions:

  Employing flexible packaging solutions, such as unit-dose packaging and pre-printed labels, can adapt to changing trial requirements and reduce the risk of labelling errors.

Current Ways of Working in Labelling	Future Enterprise Labelling
Teams working in multiple silos without much visibility	Integrated labelling and business processes across the geographies
Dependency on traditional IT support like spreadsheets	Fast & Efficient label design by business users
Time consuming reviews and approval process	Automated review and approval processes
Complexity handling issues	Managing with dynamic label content
Label change takes considerable SLA	Immediate label changes across all operations
Integration with external vendors is time consuming with significant risks	Ease in integration with external vendors with help of cloud
Tracing of phrases is difficult	Ease in tracing of phrases wherever used

How can we help you? | Infosys Advantage

In today's rapidly evolving landscape, efficient and accurate labeling is more important than ever. Infosys understands this and partners with businesses and vendors to transform their labeling processes. Infosys goes beyond just understanding clinical labelling challenges – we possess the expertise to implement all major labelling solutions from industry leaders. This means we can seamlessly integrate your chosen labelling system into your existing infrastructure, ensuring a smooth workflow. Our team of experienced professionals is well-versed in the functionalities of the platforms, allowing us to tailor the implementation to your specific needs. Whether you require a robust enterprise-grade solution or a more agile option, Infosys has the capabilities to deliver a successful implementation that maximizes the efficiency and accuracy of your clinical labelling processes. Our team of skilled resources can guide you through the entire process, from identifying the optimal solution from leading vendors to successful design and implementation.

A snapshot of our key offerings include:

- **Process mapping 'As-Is' | Diagnosing the current state**

  We collaborate with clients to assess their existing labeling practices. This comprehensive evaluation identifies areas for improvement, potential roadblocks, and hidden inefficiencies. Our vast experience helps us understand your specific challenges and goals.

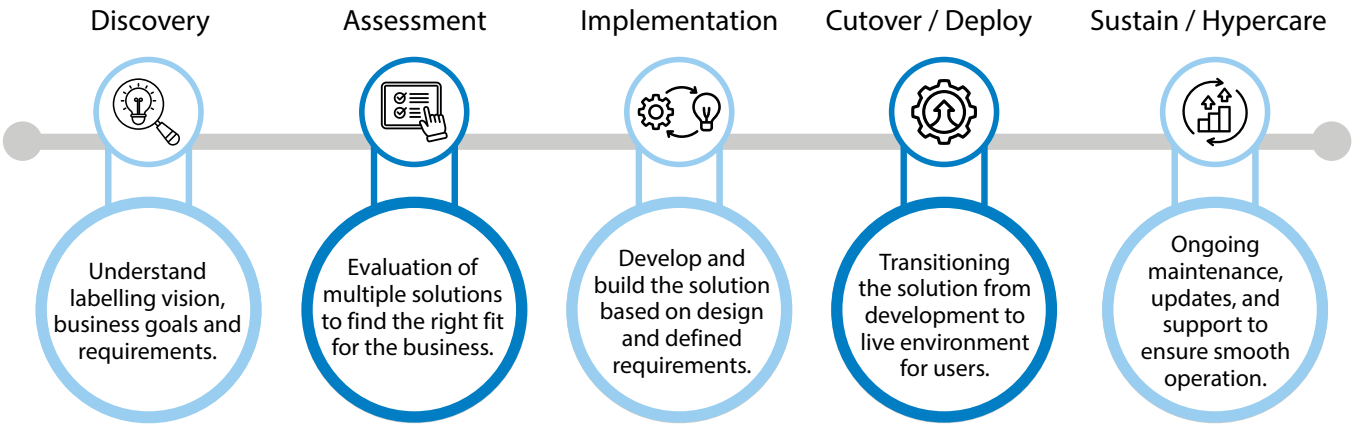
- **Charting out 'To-Be' process | Future Proofing**

  We help clients envision their ideal future state for labeling. This could involve faster turnaround times, improved data accuracy, or seamless integration with existing systems. By defining this future state, they create a roadmap for achieving success.

- **Finding the perfect fit | Unbiased Recommendations**

  Infosys leverages its extensive experience to navigate the vast market of labeling solutions. With a keen eye, we assess various options and recommend the one that best aligns with your unique needs and vision. This ensures you don't just get a new labeling system, but the right one for your business. Infosys acts as an advisor, not a salesperson, ensuring the chosen solution is the best fit.

Our end-to-end project delivery process typically involves the following phases



Also, clinical labelling navigates a complex landscape of challenges like regulatory requirements, technical nuances, and processes; hence it demands expertise and partnering with implementation partners like us ensures seamless design and implementation for your labelling needs. In conclusion, clinical packaging, and labelling play a vital role in ensuring the integrity and safety of clinical trials. By understanding the key challenges, choosing the right labelling solution and implementation partner, companies can optimize these processes, enhance compliance, and safeguard patient well-being.

About the Authors

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Srinivas is a life sciences expert with over 25 years of experience. As an Associate Partner and NextGen SAP Life Sciences Solutions Practice Lead, he helps pharmaceutical and biotech companies leverage their existing digital investments to gain more value. Srinivas focuses on helping clients leverage technology in the areas of clinical trial supply management, batch release management, cell and gene therapy, and cold chain management. He also helps companies establish operating models for transitioning from clinical development to commercial operations.

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