CELL & GENE THERAPY INSIGHTS

SPOTLIGHT

SCALING UP/OUT: COST-EFFECTIVE & ROBUST TRANSITIONING THROUGH THE CLINIC TO COMMERCIAL MANUFACTURE

COMMENTARY

Small labels, big challenges: solutions for advanced therapy labeling

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Accurate and useful labeling of advanced therapies from starting material to final drug product is critical for patient safety, compliance, and treatment delivery. In this article, the authors present label and label printing best practices for advanced therapies and discuss solutions to major challenges faced by sponsors, stakeholders, and regulators. In the context of this article, the terms "label" and "labeling" refer to in-process and final drug labels, not warning labels, package insert content, or other advisories issued and managed by regulatory agencies. As cell/tissue collection and drug product labeling are complex topics, it is also important to note and this article will focus on a few key areas, outlined below. This article will not cover other important labeling topics, including label stock, adhesives, inks, exact label content and layout (other than referring to ISBT128/SEC), label version control, label design, label testing/qualification, or label size and location.

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Today's advanced therapies are novel and hold great promise, but also pose new challenges that sponsors and stakeholders are rallying to solve. One such challenge is in-process and final product labeling. The requirement for appropriate and approved labeling is not new in biotech and pharma – it is foundational to every drug product and was recently reinforced by the FDA's guidance for gene therapy INDs [1]. Advanced therapies, however, introduce patient or donor cellular raw material into the supply chain, resulting in a much more complex process and treatment journey to produce these therapies (Figure 1).

FIGURE 1

The cell treatment journey. A complex, distributed process delivers innovative treatments.

As a critical patient-product identifier and safety measure, advanced therapy drug product labels must often be created for each individual patient and built in real time, with important and variable information added to the label at key steps in the cell collection and manufacturing process. Healthcare Providers (HCPs), in performing cell collections, now find themselves collecting starting material and are required to comply with cGMP information gathering and labeling processes. Given the patient-specific, real-time nature of advanced therapy labeling, labels can be pre-printed and shipped to clinical sites, which simplifies some aspects of label creation but can also result in storage, matching, and disposal problems. Or manufacturers can choose to have HCPs print labels at the clinical site, which reduces storage and matching problems but can cause challenges related to hardware, hospital IT compatibility, and printing equipment.

With more than 1,060 advanced therapy drug products and clinical trials operating at medical centers world-wide each with a different process and set of Standard Operating Procedures (SOPs), the need for simplified, standardized labeling processes is acute [2]. The catalyst for labeling standardization began with a public health issue related to unsafe handling of donated blood in the 1990s, and the subsequent discovery that traceback capabilities did not exist. The FDA stepped in and initiated what we now consider standard traceability of blood and tissue donation products. Building on this foundation, the International Council for Commonality in Blood Banking Automation (ICCBBA) published the ISBT 128 global standards in 1994 [3]. Cell therapy pioneers adopted

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these baseline labeling standards for human blood and tissue products at the FDA's direction. This initially served the industry well – to a point – and raised the bar on patient safety.

However, as more advanced therapies enter the clinic and approach commercial approval, it has become clear that there is a gap in labeling standards when implemented for today's advanced therapies. The ISBT 128 and SEC standards are in effect for blood and tissue collection or donation activities, but the standards were not established with the expanded and complex advanced therapy supply chain in mind, where traceability from order through manufacturing, treatment and beyond is required [4–6]. As a result, a cross-industry standards updating effort is now underway, which will be discussed later in this article.

Label issues are a major reason for the FDA rejecting or questioning New Drug Applications (NDA) and Biologics License Applications (BLA) [7]. Revisiting proven best practices related to donor material and drug product labeling will help sponsors and stakeholders bridge the gap between existing standards and emerging standards, and enable manufacturers to bring life-saving advanced therapies to patients in need more safely and efficiently.

SEVEN PROVEN PRACTICES

Experience demonstrates that certain practices lead to successful labeling and support the ability to deliver safe treatments to patients. The following top seven labeling practices are proven to work across multiple therapies, for both clinical and commercial phase products:

1. Standardized formats
2. Patient privacy and patient identifiers
3. Complete Chain of Identity (COI) and Chain of Custody (COC)
4. Multi-language capabilities
5. On-demand label printing
6. Printing to any existing and approved printer
7. Collaboration with regulatory agencies

Standardized formats

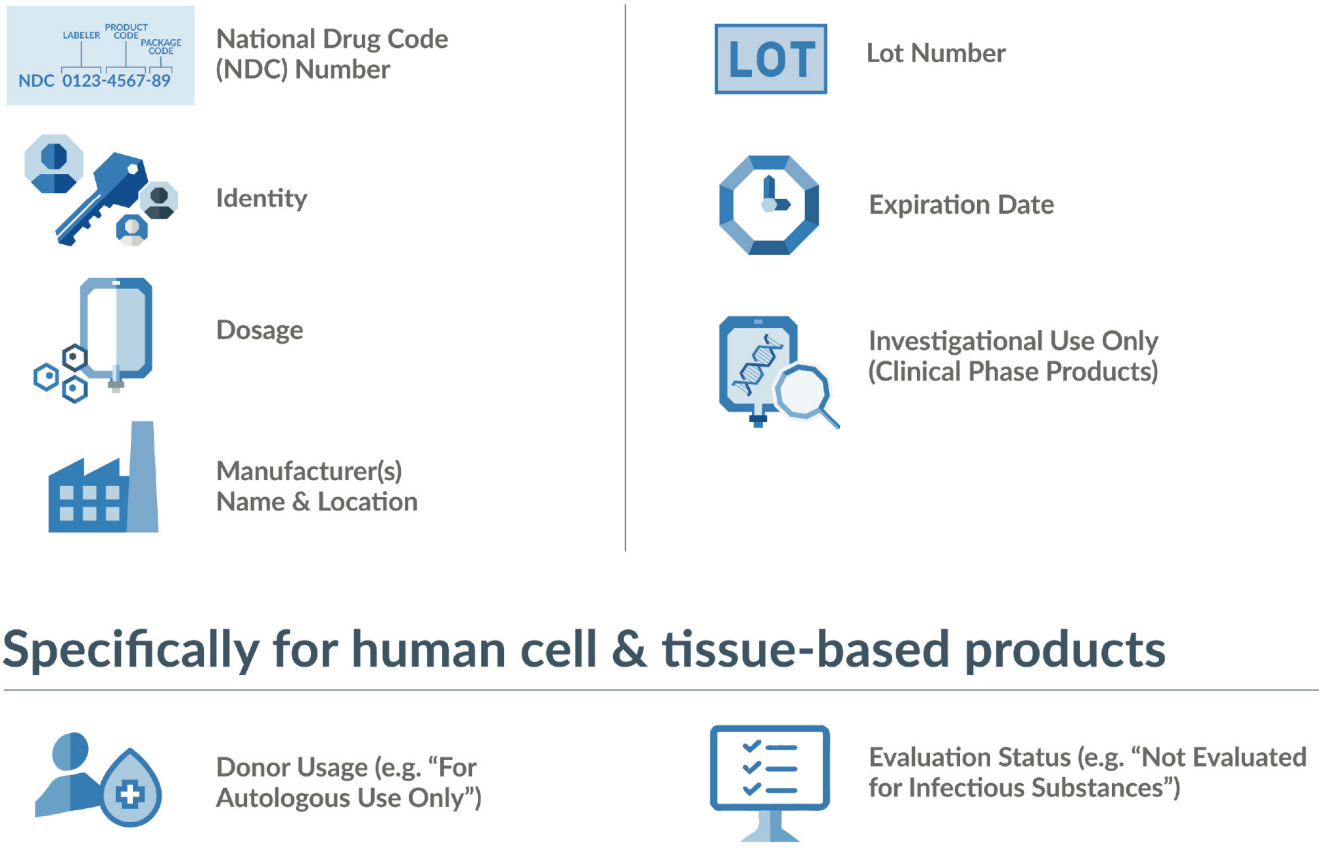
Standardization across materials, products, and processes decreases risk and errors while increasing efficiency and scalability. This is foundational to cGMP and especially important in a distributed ecosystem such as the advanced therapy supply chain, where many partners are not accustomed to cGMP practices. When established standards exist, utilizing them is a key to compliance. The FDA has certain baseline requirements for labeling (see Figure 2 [9–12]), which is part of basic cGMP operations and, as discussed in the introduction, there are additional global standards that currently exist – ISBT 128 and the SEC – for labeling blood and tissue products and providing traceability [4–6,8]. Compliance with these standards is often mandatory, with the primary aim of ensuring patient safety through blood and tissue product traceability.

An additional consideration is the importance of providing label information via scannable barcodes and human readable formats. Space is at a premium on labels, and in this digital age, it is tempting to count on reading barcodes with scanners. But maintaining continuity and integrity of patient identifiers across the entire supply chain is paramount for avoiding product mix-ups. That may mean having the ability to verify information without the benefit of a digital tool.

The independent, non-profit Standards Coordinating Body is facilitating an industry-wide working group to update the ISBT 128 standards for apheresis collection labels and establish minimum label requirements for apheresis cell collections (Figures 3 & 4) [13]. More detail on this initiative can be found later in this article.

FIGURE 2

Finished drug product label.



Key baseline requirements by the FDA ensure consistency and standardization [9–12].

Patient privacy & patient identifiers

As a critical support for patient safety, labels must contain some patient-identifying information. The nature of that information, such as name, initials, or date of birth, is a frequent topic of debate. Alongside patient safety, patient privacy is also important.

Amid privacy concerns, it's important to keep in mind that name, initials, and date of birth are typical patient identifiers used in medical centers and for prescriptions to ensure that the right product is administered to the right patient. This is part of standard practice on drug product packaging, and HCPs are trained to use this information appropriately. This practice is demonstrated in the use of patient information on approved cell therapy product labels such as Provenge® [14], Yescarta® [15], Kymriah® [16], and Zynteglo® [17] (EMA approved).

The European Union's (EU) General Data Protection Regulation (GDPR) has been reshaping the way data is handled across every industry sector, including clinical research, by strengthening and standardizing the protection of personal data. Navigating GDPR and traceability requirements in the EU may require further expert help and collaboration with regulators – a best practice discussed in more detail later.

Concerns over visibility of patient information on external secondary and tertiary packaging (e.g. shipping labels) that is more broadly viewable can be addressed with anonymized information. Additional persistent, transparent patient identifiers can be created and tracked in ways that are consistent with

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patient privacy regulations. One such set of identifiers is commonly referred to as Chain of Identity, or COI, which we'll discuss next.

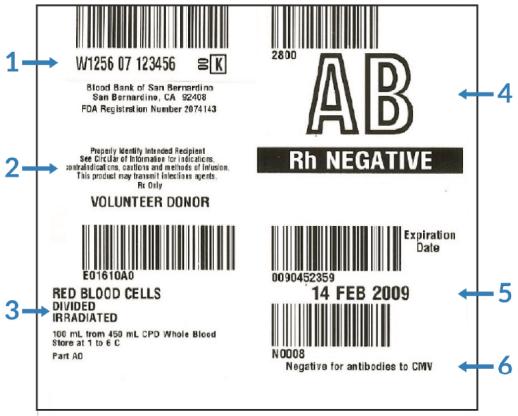
Chain of Identity (COI) & Chain of Custody (COC)

COI and COC are the cornerstone of three important success factors for any drug product – patient safety, regulatory compliance, and operational efficiency (Figure 5). These 'chains' are part of the expanded lot genealogy for advanced therapies, a key aspect of a Quality Management System, and of the traceability required by regulatory authorities [1,18]. Labels are critical for supporting COI and COC at every step of the supply chain from collection to treatment. Labels provide important data

FIGURE 3

ISBT label format.

1. Donation Identification Number
2. Product Information or Collection Date and Time
3. Product Code and Description
4. ABO/Rh groups
5. Expiration Date and Time
6. Special Testing (optional)

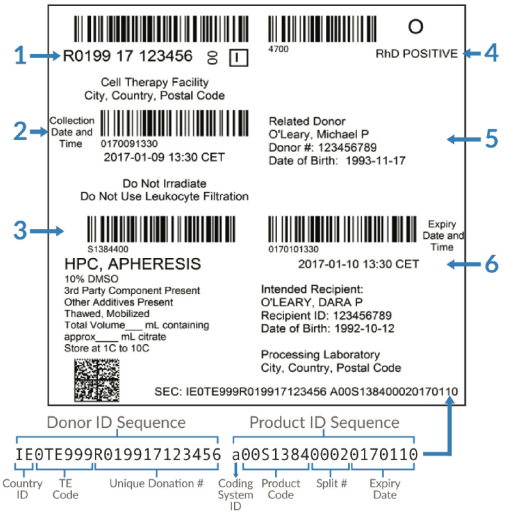


ISBT 128-compliant label formatting guidelines (revisions in process to better address the needs of cell therapy collections) [5].

FIGURE 4

SEC-compliant label formatting guidelines [6].

1. Unique Donation Number
2. Collection Date and Time
3. Product Code
4. ABO/Rh groups
5. Donor Identification
6. Expiry Date and Time



SEC label format.

FIGURE 5

COI and COC defined.

Chain of Identity

A patient's core unique identifier created for the permanent, transparent association of patient-specific data points to tissue and/or cells from order through product(s) creation, fulfillment, and post-treatment monitoring (including collection, manufacturing, administration).

Chain of Custody

Permanent and auditable data capture from the origin of tissue and/or cell collection through product administration. The data identifies the staff that handled the product, actions performed by those staff, and the location/date/time of those actions (who, what, when, where, and how).

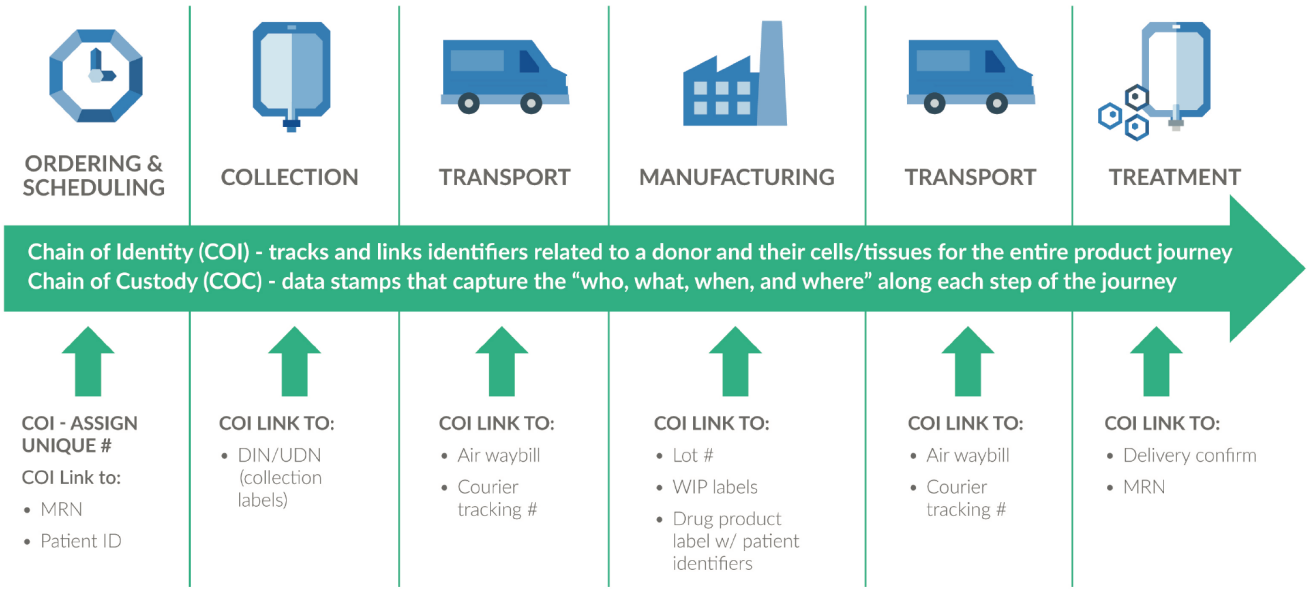
Chain of Identity and Chain of Custody are an essential part of patient safety, compliance, and the manufacturing journey.

and identifiers – via both human-readable and machine-readable formats – which are linked to essential information that ensure the right product is in the right place and undergoing the right process for the right patient (Figure 6).

The established best practice for advanced therapy COI and COC tracking is the use of

FIGURE 6

Priority #1: Patient safety with COI, COC.



The numerous data points and hand-offs in the product journey make managing COI and COC a complex task. Digital tracking reduces risk and more easily meets compliance requirements.

Expanding traditional Quality Management Systems (QMS) for the advanced therapy supply chain.

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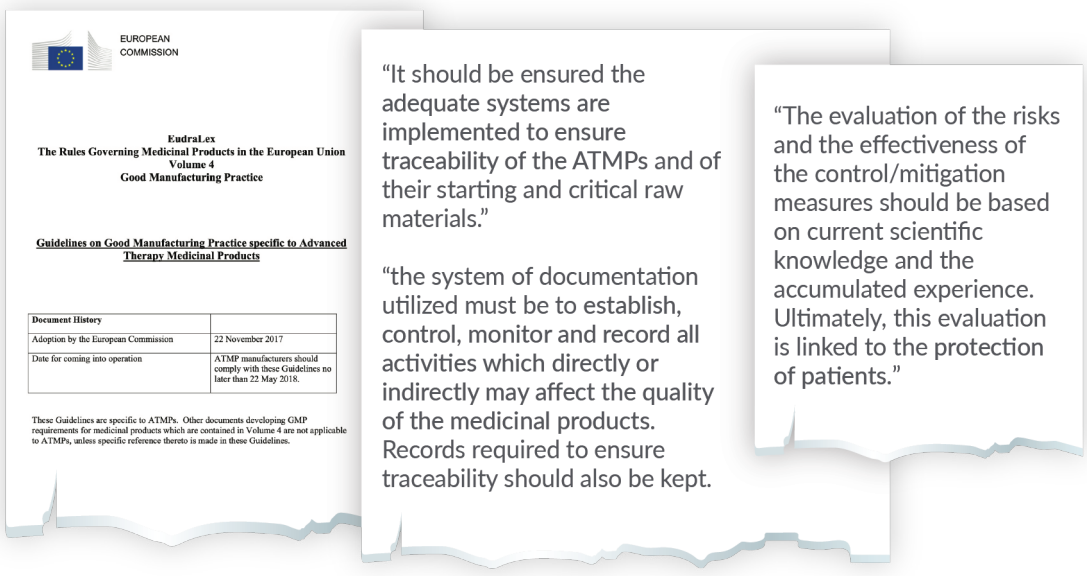
FIGURE 7

Regulatory guidance from the European Medicines Agency, 2017.



Guidelines related to Good Manufacturing Practice (GMP) specific to advanced therapies [18].

a digital system. The numerous touch points and physical locations in the product journey make manual tracking time-consuming and error-prone. It is too risky to leave patient safety to chance in this way. Additionally, routine compliance becomes onerous, and product approval may be a challenge. Regulatory reviewers want an application to demonstrate that traceability is well in hand (Figure 7) [1,18]. From an operational standpoint, the cost and resource utilization to maintain manual traceability is not efficient or scalable beyond a small number of patients or with a simple supply chain process.

Multi-language capabilities

The complex, distributed ecosystem of advanced therapies often means supply chain partners and patients are located in many geographic regions, both within the United States and across the globe. The need for starting material and drug product to cross borders, or to be produced and delivered locally in a region different from that of the biopharma company, presents additional labeling challenges. Labels must be in compliance with local, national and international requirements, depending on the situation, and must also be relevant and useful to those handling and processing the material or product. One important aspect of this is the ability to generate raw material, in-process, and final product labels in multiple languages.

Ensuring patient safety means that personnel at local care sites and other supply chain partners must be able to easily and definitively read key pieces of information on labels, meaning the information must be presented in the appropriate language(s). This is challenging due to the limited physical space available on many labels, the sheer number of possible languages and language formats a company may need to support (left to right, right to left, top to bottom), and the variability in translations. Working with experienced partners and regulators on label design, formatting, and printing helps ensure that the essential information is included, presented in only the correct languages required for that

geography, and that the physical space on the label is used efficiently.

Solutions such as Vineti's Personalized Therapy Management Platform (PTM; Vineti solution) [19] come equipped and ready to support multi-language labels (including character based languages), providing the ability to deploy and maintain standardized, compliant labeling across multiple geographies for local use. Additionally, establishing or procuring approved and standardized phrase libraries ensures accurate, consistent translations every time and cuts significant time out of the process for creating, reviewing, and revising labels. The benefits of proactively tackling multi-geography labeling challenges pay off early, even if there are only a few regions involved. As clinical trials progress and expand, and a therapy moves toward commercialization, it can be difficult to scale one-off or manual processes. Having established multilingual capabilities early on to scale up and out across geographies will save time and money getting therapies approved and to the patients who need them most.

On-demand label printing (vs print & ship)

One of the decisions that advanced therapy manufacturers face is whether to print labels in advance and ship them to the partner sites, or establish the capabilities for partner sites to print labels on-demand, prior to, or during, processing. This seemingly small decision has significant factors to consider, and is a major consideration as therapy delivery scales. For many reasons, on-demand label printing is the recommended and most compliant option.

Most importantly, patient safety is easier to ensure with on-demand label printing. Patient ID verification is linked to label printing and the patient is paired with their labels from the outset. On-demand is also much simpler to manage from a compliance and supply chain standpoint. Label reconciliation is a key cGMP compliance activity to prevent product mislabeling (or product mix-ups) [20]. Every label must be accounted for, and pre-printed labels create additional touch points and opportunities for labels to be lost and unverified. Operationally, pre-printed labels create a whole new 'supply chain' that must be managed, requiring additional and costly resources, and putting additional and unnecessary pressure on an already time sensitive process.

Printing to existing printers

There have been different approaches and challenges related to label printers as well. One option was to deploy dedicated printers for each therapy to partner sites. This may be problematic in some cases, because additional complexity and cost is unnecessarily introduced into the supply chain, there are additional security considerations, and scalability is hampered. Ecosystem partners such as HCPs and clinical sites may have limited space for additional hardware, and deploying dedicated printers to individual partner sites involves installation, training, logistics, and maintenance requirements that are time-consuming, personnel intensive, and expensive.

A more sustainable and scalable model is to utilize existing printers at partner sites for label printing. This is time and money saving

FIGURE 8

FDA's mission.

"The Food and Drug Administration is responsible for protecting the public health by assuring the safety, efficacy and security of human and vetinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation."

The FDA's mission extends to essential safety components of drug products, including labeling [21].

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for both the partner and the drug developer and simplifies one aspect of a complicated process. It is also more secure to utilize hardware already in operation within a site's IT system, and modern cloud-based solutions provide enhanced security and remote management. This ability is a feature of Vineti's Personalized Therapy Management platform (PTM), which provides a turnkey solution for label printing (for more information on PTM, please see [19]).

Collaboration with regulatory agencies

The FDA's mission is "…protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices…" (Figure 8) [21].

One important way the agency carries out this mission is through the requiring and approving of in-process and final product labeling. It is worth mentioning again that label issues are cited by FDA regulators as a major reason for rejecting or questioning New Drug Applications (NDA) and Biologics License Applications (BLA).

Frequent collaboration with regulatory agencies cannot be stressed enough. This helps ensure filing acceptance and avoids the many potential pitfalls for advanced therapy labels. Beginning with IND filing, regulatory guidance puts emphasis on the importance of labeling, further indicating that early focus and collaboration on labeling is smart [1]. If left until late in the process, labeling processes and details may present an unexpectedly time-intensive, complex issue to solve. This holds in the United States, and is also important globally, where there may be multiple agencies involved and differences from region to region. Each drug product will have something unique that will need to be addressed specifically by regulators. It is better to ask questions up front, rather than to wait until the application is filed. Early conversations and feedback during product development can eliminate clinical holds and costly, timeline-breaking re-work – in addition to delays in getting treatment to critically ill patients.

TRANSLATIONAL INSIGHTS: STANDARDS FOR SCALE

As advanced therapies grow in number and reach, sponsors and stakeholders are developing standards to enable a patient-centric drug product ecosystem. The Standards Coordinating Body (SCB) is conducting FDA-funded work to carry out standards directives in the 21st Century Cures Act, Section 3036. As part of its work on advanced therapy standards, the SCB, in partnership with ICCBBA, is building on the existing labeling standards for cell collection products and modifying them to accommodate the current state – for autologous and allogeneic products – to help prepare the industry for future success [22].

This SCB industry working group on labeling is composed of a variety of ecosystem stakeholders and subject matter experts who can provide the perspective and experience needed to develop suitable standards [23]. Some of the standards being evaluated in relation to apheresis collection labels include a working common definition of COI and COC, label content, layout, required data, and data formats. Timelines for gathering final input and publishing the updated standards are being determined in collaboration with ICCBBA. To see the draft standards document, please visit the ICCBBA website [24]. To learn more about this important effort and get involved, please contact SCB [25].

Looking to the future, such standards will become more important than ever. The number of advanced therapies in the R&D pipeline is increasing, with a goal of making more therapies safer and capable of being delivered on an out-patient basis. Scaling will involve expansion more broadly into community-based settings. This accessibility across all

types of medical centers is critical for patients. Therefore, supporting the ability for smaller, more distributed clinical sites to collect starting material, deliver treatments, and manage patient-specific labels is required for greater access. Simple, flexible, compliant label printing is one important piece of this model. By following proven practices and working together to develop and implement standards, advanced therapy sponsors and stakeholders will take a critical step towards a future of greater advanced therapy access for all.

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