Standard Labeling for Apheresis Collection Products for Sponsor Cellular Therapy Manufacturing

Introduction

The Deloitte Next Generation Therapies Industry Working Group Meeting in September 2019 identified the need to focus on standardization of labeling of collection products for cell therapy manufacturing.

Based on this, a decision was made to establish a focus group comprised of industry stakeholders and facilitated by the Standards Coordinating Body to work on standardizing the minimum elements required for labeling. This document is the initial output from the focus group and is circulated for comment. Comments should be submitted to: Dawn Henke of the SCB (dhenke@regenmedscb.org) by March 20, 2020.

Focus group membership

The following organizations are represented in the focus group:

bluebird bio, Glaxo Smith Kline, Gilead Sciences, Johnson & Johnson, Juno Therapeutics, Kite Pharma, Legend Biotech, Be-the-match, Deloitte, AABB, FACT, ICCBBA, Standards Coordinating Body, Trakcel, Vineti, and subject matter experts in apheresis nursing and quality assurance.

Background

Apheresis collection of starting products for use in cellular therapy manufacturing for clinical trials and commercial therapy is performed in blood center or hospital apheresis suites under contractual arrangements with sponsors. Currently sponsors have different labeling requirements for these apheresis collections and this causes challenges for the collection centers, particularly in situations where a collection center collects on behalf of multiple sponsors. By providing standardized, consistent labelling to all apheresis collection bags destined for further manufacturing by a sponsor company, the risk of misinterpretation of patient data once the bags depart the blood center or hospital apheresis suites (leaves hospital walls) can be reduced.

The products prepared from these collections undergo complex manufacturing steps and are tailored to a specific recipient or group of recipients. In many cases the donor of the collection product is the same person as the recipient of the final product. Ensuring a robust chain of identity and secure systems for patient identification are essential patient safety requirements.

It is therefore beneficial to develop a standard approach to labeling that is compatible with labeling equipment and software currently in use, and supports the use of electronic data capture to eliminate the risk of manual transcription errors.

Many of these apheresis collection sites are likely to be collecting other apheresis products for clinical application and these will be labeled with ISBT 128.

The ISBT 128 label printed to affix to an apheresis collection set base label is a standard nominal 4” x 4” (100mm x 100mm) label. These labels are widely used for final labeling of blood and cell therapy products and thus are readily available to the label application developers. They use appropriate materials and adhesives to be compatible with blood and cell product storage.

Example:
Sponsor information is currently printed on separate labels and these vary in both design and content depending on sponsor specifications.

**Proposed Solution**

Basing the apheresis label for further manufacturing design on the same cellular therapy standard label will minimize the impact on collection centers.

The traceability information on the standard ISBT 128 label is on the left hand side of the above label. A hybrid label based on the same size and stock materials would allow the ISBT 128 information to be retained in a similar position to other CT product labels on the left hand side of the label, and sponsor information to be located on the right hand side of the label.

It is planned to standardize the content and layout of the sponsor section.
Hybrid Clinical Trials Label Example 1 – Autologous

For Clinical Trial Use Only
For Autologous Use Only

Patient ID: XYN127654
Patient Name: DOE, John William
Patient DOB: 1999-06-01

Expiration Date/Time:
2020-01-17 13:40 EST
(2020-01-17 18:40 UTC)

Collection Center Site No:
Receiving Facility Info
Protocol: NCT99999999

COI:
123ABC456DEF789GH1011

MNC, APHERESIS
For Further Processing
Total Volume ___ mL containing
approx ___ mL Citrate
Store at 1 to 10 °C

Hybrid Clinical Trials Label Example 2 – Unrelated Donor (EU)

For Clinical Trial Use Only
Unrelated Donor

GRID: 9991 0120 7043 3201 632

Patient ID: XYN127654
Patient Name: DOE, John William
Patient DOB: 1999-06-01

Expiration Date/Time:
2020-01-17 13:40 EST
(2020-01-17 18:40 UTC)

Collection Center Site No:
Receiving Facility Info
Protocol: NCT99999999

EudraCT: 2019-999999-01
COI:
123ABC456DEF789GH1011

MNC, APHERESIS
For Further Processing
Total Volume ___ mL containing
approx ___ mL Citrate
Store at 1 to 10 °C
Hybrid Clinical Trials Label Example 3 – Related Donor

For Clinical Trial Use Only
Related Donor
Donor Name: Jane Doe
Donor DOB: 1980-01-31

Patient ID: XXN127654
Patient Name:
DOE, John William
Patient DOB: 1999-06-01

Expiration Date/Time:
2020-01-17 13:40 EST
(2020-01-17 18:40 UTC)

Collection Center Site No:
Receiving Facility Info
Protocol: NCT99999999
COI:
123ABC456DEF789GHI1011

MNC, APHERESIS
For Further Processing
Total Volume ___mL containing
approx ___mL Citrate
Store at 1 to 10 C

Sponsor Info Area

Hybrid Clinical Trials Label Example 4 – Beyond Clinical Trials

For Autologous Use Only

Patient ID: XXN127654
Patient Name:
DOE, John William
Patient DOB: 1999-06-01

Expiration Date/Time:
2020-01-17 13:40 EST
(2020-01-17 18:40 UTC)

Collection Center Site No:
Receiving Facility Info

COI:
123ABC456DEF789GHI1011

MNC, APHERESIS
For Further Processing
Total Volume ___mL containing
approx ___mL Citrate
Store at 1 to 10 C

Sponsor Info Area
Text specification for right hand side of label

Clinical Trial Message

For Clinical Trial Use Only – this text shall appear if the product is in clinical trials.

Donor Characteristic

For Autologous Use Only – this text shall appear if the product is for autologous use only.

Unrelated Donor – this text shall appear if the product is derived from an unrelated donor. The GRID of the unrelated donor should be printed below this statement.

Related Donor – this text shall appear if the product is derived from a related donor. The donor name and date of birth may be printed below this statement.

Patient Identification

A patient identifier shall be printed. This shall be the sponsor/manufacturer assigned patient identifier.

Patient name should be printed. Name should be printed with family name first followed by a comma and then given names. For example: DOE, John William.

Patient date of birth should be printed. Date shall be represented in either ISO 8601-2004 extended format or in the format day month year with month representation as three alpha characters and year using four digits.

1976-05-13

13 MAY 1976

The ISO 8601-2004 representation is recommended as it provides a language neutral internationally recognized date.

If the day month year representation is used it is recommended that the month should be in upper case letters using the following values: JAN, FEB, MAR, APR, MAY, JUN, JUL, AUG, SEP, OCT, NOV, DEC. Translation of the month representation is not recommended due to the potential for confusion in an international context.

Expiration Date and Time

Expiration date, and where appropriate expiration time, shall be printed.

Dates shall be printed in compliance with ISO 8601-2004 extended format (YYYY-MM-DD) or in the format day — month — year. The ISO 8601-2004 representation is recommended as it provides a language neutral internationally recognized date.

If the day month year representation is used it is recommended that the month should be in upper case letters using the following values: JAN, FEB, MAR, APR, MAY, JUN, JUL, AUG, SEP, OCT, NOV, DEC. Translation of the month representation is not recommended due to the potential for confusion in an international context. The year shall be a four-digit numerical representation.

Times shall be printed based on a twenty-four hour clock with a colon placed between the hours and minutes.
When the default time of 23:59 is encoded, the time does not have to appear as text, although it is acceptable if it does appear.

If the product is to be shipped across time zones, AABB and FACT-JACIE Standards require that the text expiration date and time include the local time zone. In addition, the ISBT 128 Standard requires that the label also include the Coordinated Universal Time (abbreviated UTC, previously known as Greenwich Mean Time, or GMT) when the product is to be shipped across an international time zone.

The UTC shall be printed beneath the local time in parentheses with the designation “UTC.” Italics may also be used to clearly differentiate UTC from local time. For example:

Expiration Date/Time:
15 JAN 2020 09:15 CST
(15 JAN 2020 15:15 UTC)

OR

2020-01-15 23:15 CST
(2020-01-15 15:15 UTC)

(Note: It is recognized that local time zone designations may have little meaning internationally since two time zones may have the same abbreviation [e.g., CST can be China Standard Time (UTC+08 hours) or Central Standard Time in North America (UTC-06 hours)]. However, the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG) believe that local time zones are more readily interpreted within a continent. For products shipped to different continents, UTC should be used to interpret time.)

Location Identifiers

A sponsor/manufacturer allocated collection center site identifier may be printed.

A sponsor/manufacturer allocated receiving facility identifier may be printed.

Other specified text

Any other text specified by the sponsor/manufacturer may be included. For example: “Autologous Apheresis for further use in manufacturing of XXXXXX Drug Product”

Protocol and Trial Identifiers

The sponsor/manufacturer protocol identifier shall be printed.

Other identifiers, such as the EudraCT clinical trial identifier may be included.
Chain of Identity Identifier

The chain of identity identifier shall be printed.

Electronic AIDC symbol

A Data Matrix two-dimensional code should be included carrying an ISBT 128 Compound Message that includes the Donation Identification Number, Product Code, Expiration Date/Time. When the Chain of Identity code has been standardized this should also be included in the compound message.

Sponsor/Manufacturer Identification

The sponsor/manufacturer should be identified using a name or logo.