Tracking and Tracing- the Glasgow System

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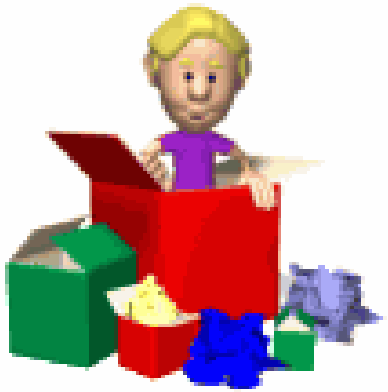
Agenda

- The Barcodes
- The Software
- Tracking and Tracing (Tissue Trace™)
- The Quality delivered



The Barcodes
Choice of standard

- Choice of standard GS1 or ISBT 128 (ICCBBA)
- Both not for profit organisations.
- Both have healthcare solutions.
- One allows tracking from Donor to patient.
- Both work in collaboration not to duplicate effort within healthcare.

ICCBBA Objectives

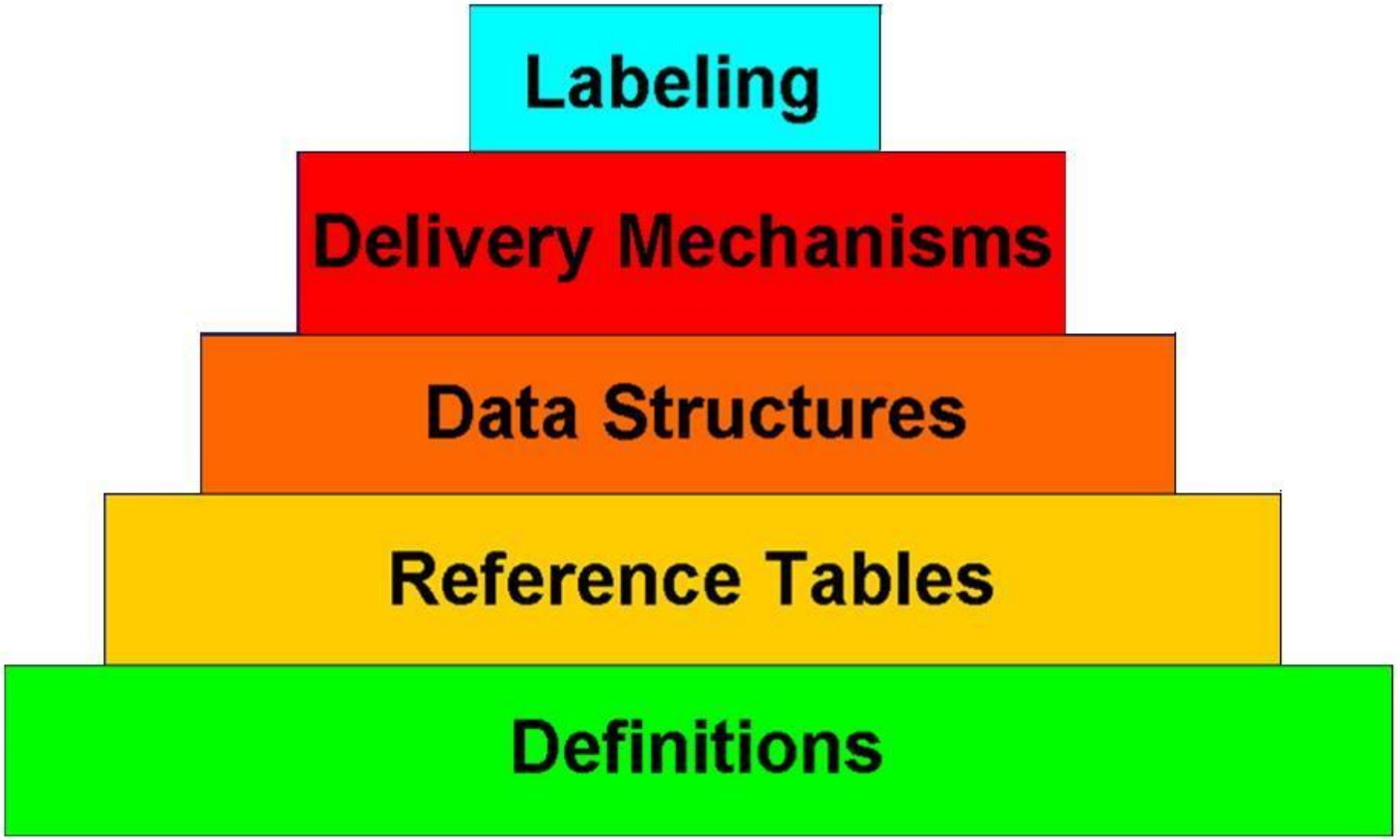
To provide a standard information environment that:

- supports the open movement of blood, tissues, cellular therapy, Milk products around the world, or locally within a country in such a way that critical information is rapidly, accurately and unambiguously communicated;
- satisfies regulatory requirements for traceability and retention of information.

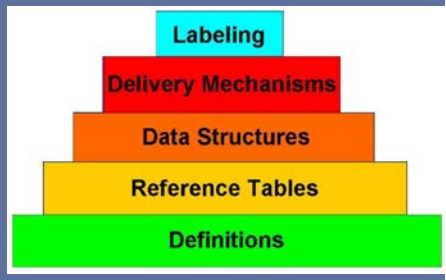
What is ISBT 128

- *ISBT 128* is an information standard for transfusion and transplantation
- Developed for transfusion by ISBT in 1994
- Extended to support Tissue Banking and Cellular Therapy in 2000
- Defines:
  - Definitions and Reference Tables
  - Data Structures
  - Delivery Mechanism and Labelling Guidance

What is an Information Environment?



Information Environment Model



Class

Human Milk

Attribute Groups

Preservation technique and storage conditions

Describes the preservation technique and/or the conditions under which the product will be stored

Processing Status

Indicates if a product is being held for further processing

Pathogen reduction

Describes the method of sterilization or decontamination of the product

Donor-intended recipient relationship

Describes the relationship between the donor and the intended recipient

Additives for nutritional products

Describes supplements added to nutritional products

Pooled

Describes a process where product from multiple donations is combined

What is an Information

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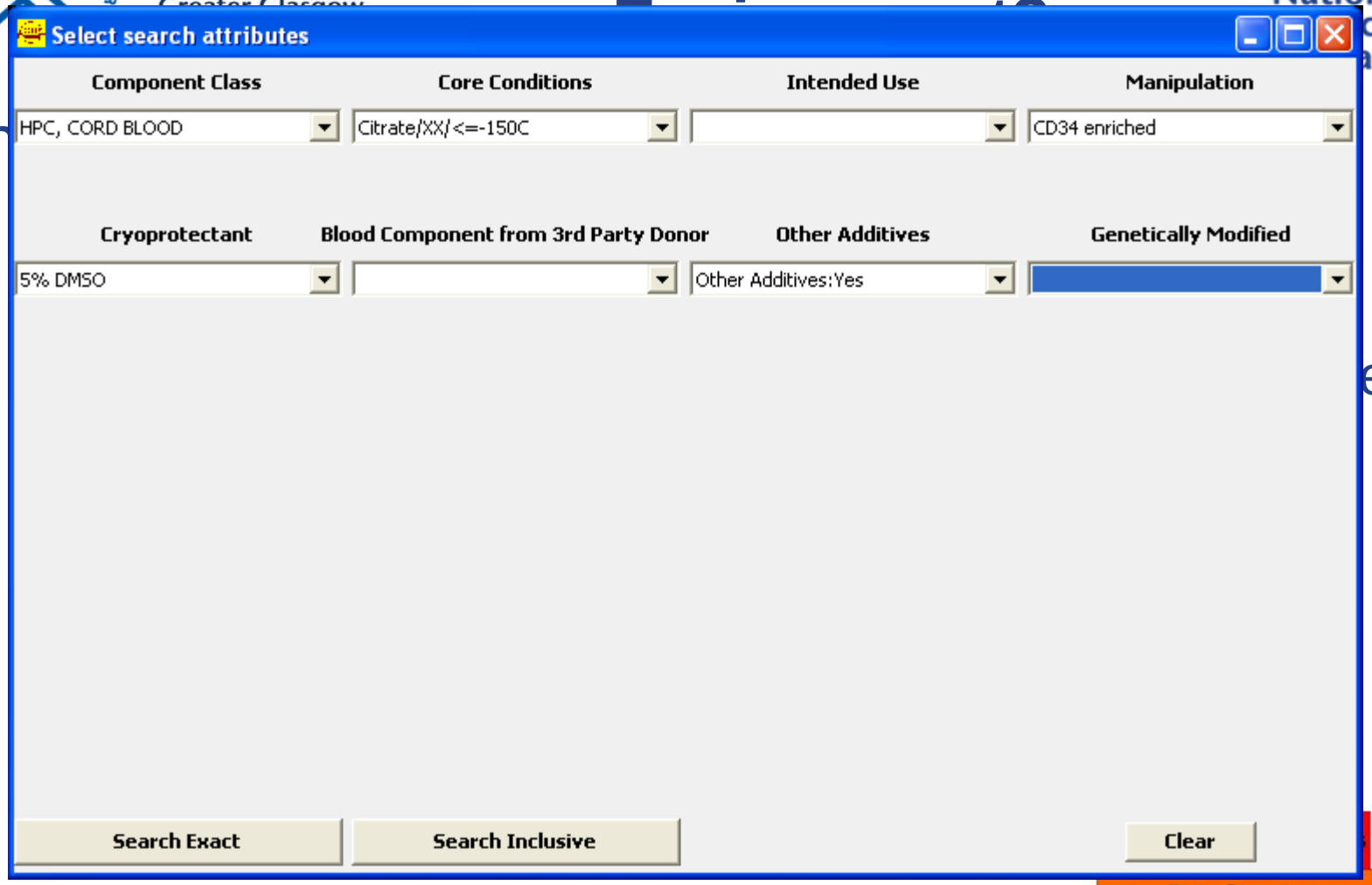
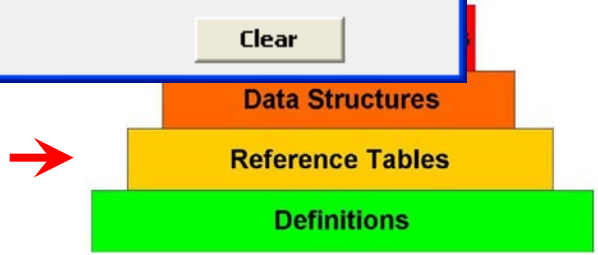
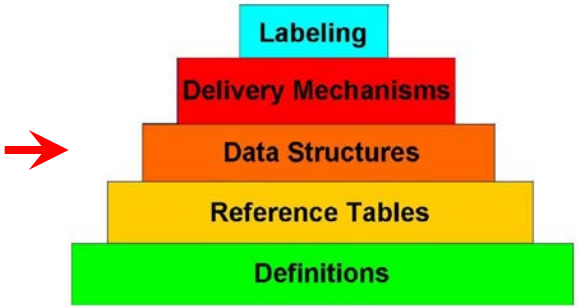




What is an Information Environment?

The Basic Elements

- Data Structures
  - Technical definitions for data transfer
  - Provide the ‘context’ for information
  - Allow independent systems to communicate
  - Developed and maintained to meet community needs

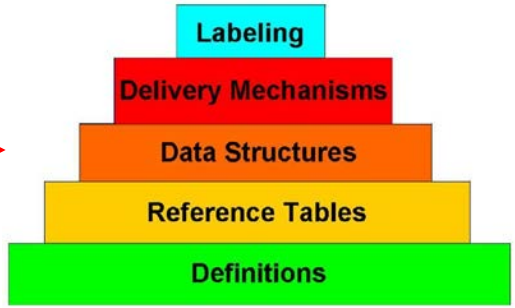


Donation Identification Number

G1517 02 123456 LO M

- Comprises 4 elements:
  - Facility identification code
  - Year indicator
  - Sequential number
  - Flag characters
- Manual entry check character

=G15170212345601



Compound messages used in 2D barcodes

Example:

A compound message using defined structured message 003 would look like:

=+04003=G15170612345600=%5100=<E0001000&>0060252359

where

=+04003 identifies this as a compound message of four data structures using the format defined for structured message type 003;

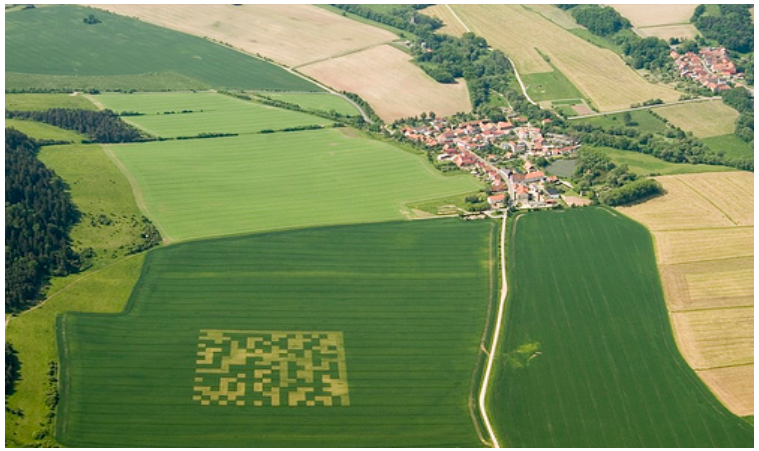
=G15170612345600 is the donation identification number data structure;

=%5100 is the blood group code data structure;

=<E0001000 is the product code data structure;

&>0060252359 is the expiration date and time data structure.

Bernd Hopfengärtner
(Hello World)

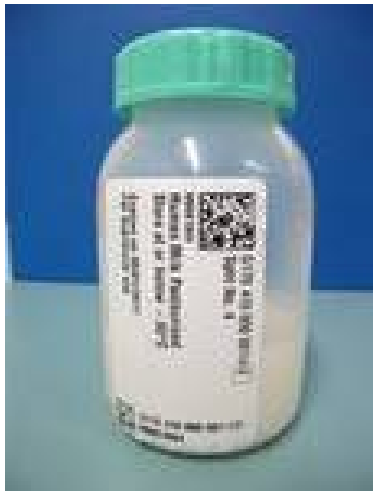


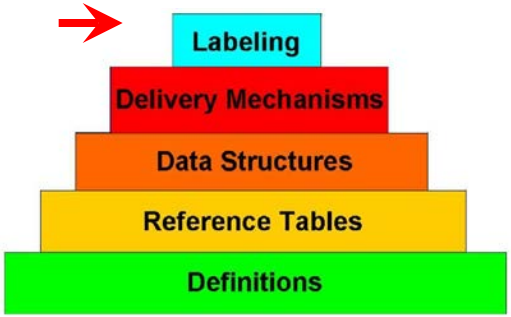
What is an Information Environment?

- Delivery Mechanisms
  - Means of delivering information
  - Bar coding, Radio frequency tags (RFID), RSS codes (GS1 codes)
  - Need the underlying elements to provide the required functionality

What is an Information Environment?

- Labeling
  - Defines means of providing information in the right place and format
  - Must ensure consistency between electronic and eye-readable information





Ensuring the 5 Patient Rights

The *right* product

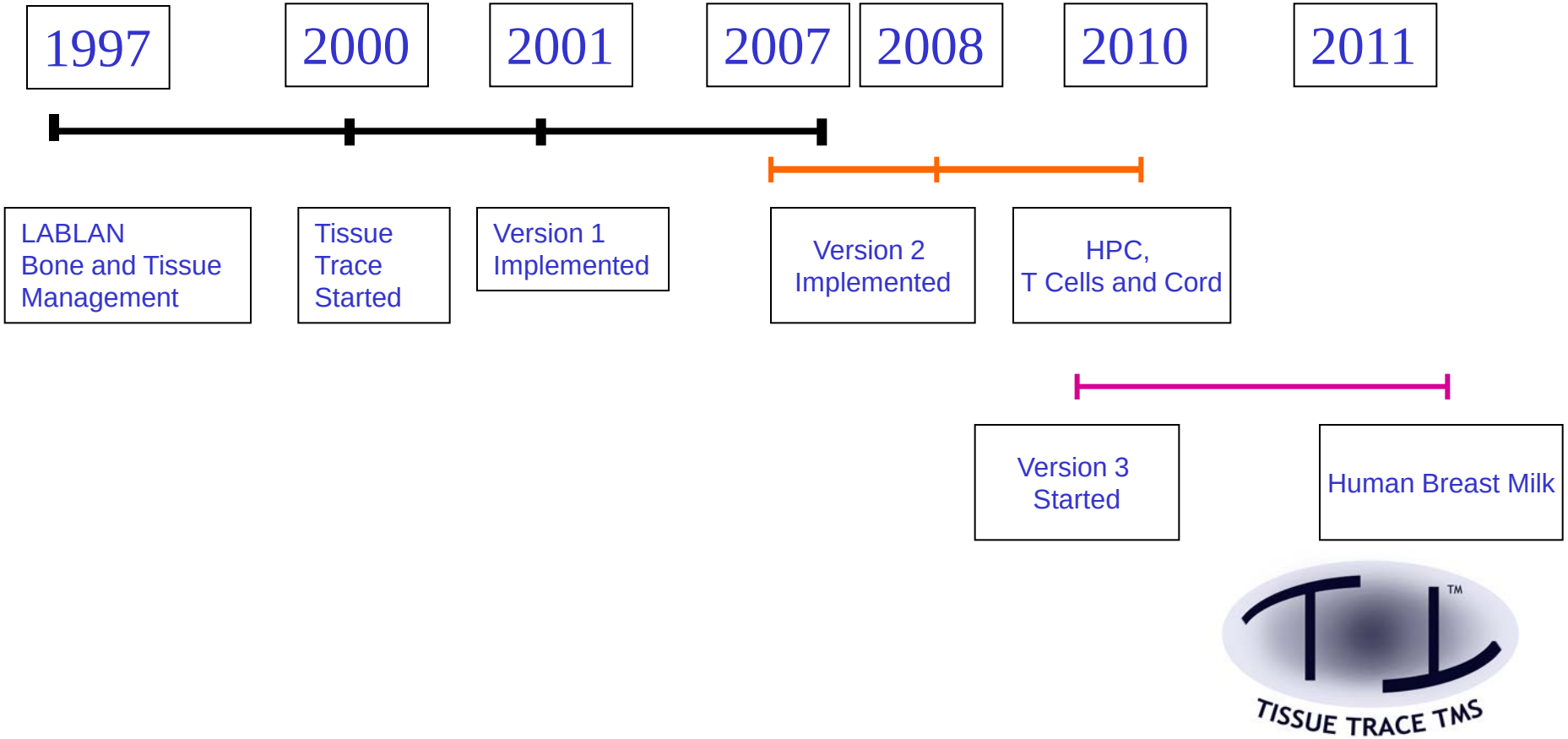
The *right* route

The *right* dose

The *right* time

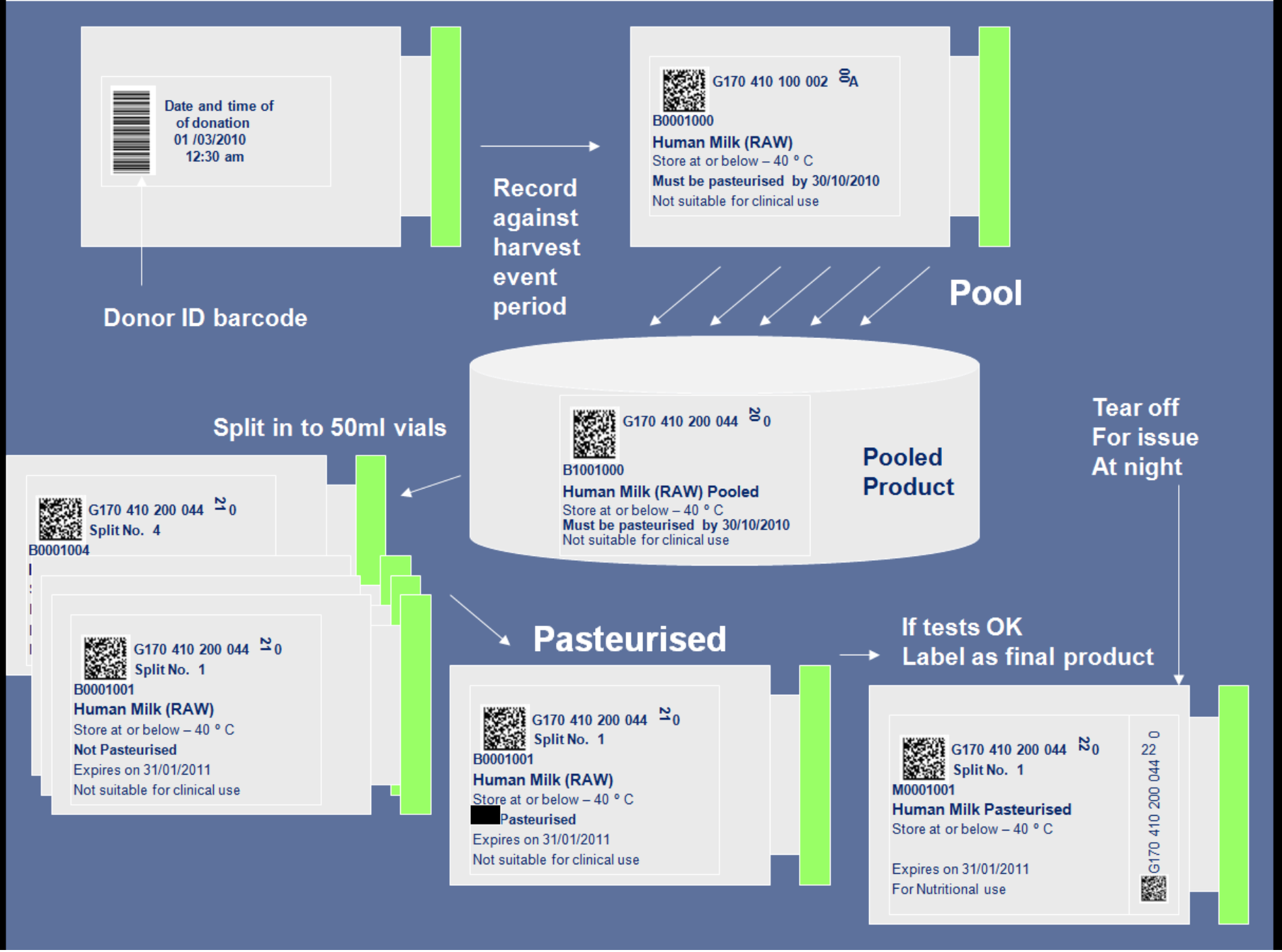
The *right* patient

The Software Tissue Trace™



- What does it do

- Provides audit of human tissue products from donor to patient. (Who / What / Where / When)
- Electronic release of product.
- Print on demand labels.
- Electronic update of test results from electronic interfaces.
- Provides processing management. (Pooling /Splitting)
- Controls test management.
- Concessionary release management.
- Product reservation.
- Product confirmation of use.


Date and time of
of donation
01 /03/2010
12:30 am
Donor ID barcode
Record
against
harvest
event
period
G170 410 100 002 00A
B0001000
Human Milk (RAW)
Store at or below – 40 ° C
Must be pasteurised by 30/10/2010
Not suitable for clinical use
Pool
G170 410 200 044 20 0
B1001000
Human Milk (RAW) Pooled
Store at or below – 40 ° C
Must be pasteurised by 30/10/2010
Not suitable for clinical use
Pooled
Product
Split in to 50ml vials
G170 410 200 044 21 0
Split No. 4
B0001004
G170 410 200 044 21 0
Split No. 1
B0001001
Human Milk (RAW)
Store at or below – 40 ° C
Not Pasteurised
Expires on 31/01/2011
Not suitable for clinical use
Pasteurised
G170 410 200 044 21 0
Split No. 1
B0001001
Human Milk (RAW)
Store at or below – 40 ° C
Pasteurised
Expires on 31/01/2011
Not suitable for clinical use
If tests OK
Label as final product
Tear off
For issue
At night
G170 410 200 044 22 0
Split No. 1
M0001001
Human Milk Pasteurised
Store at or below – 40 ° C
Expires on 31/01/2011
For Nutritional use
22 0 G170 410 200 044

Security

- Users all have login accounts.
- Accounts have access based on requirements.
- Security of access will be through the use of complex passwords at login. E.g. Use of Alpha, Numeric, Upper and Lower case and some syntactical characters like ‘&:*’
- System will prompt users to change passwords on a defined period (system parameter, usual is 60 days)

Track and Trace with TT™

- Donor Management
  - Donor Registration
  - Donor Edit
  - Milk Bottle label print.
    (Unique label with donor identification barcode and areas to record date and time the milk was expressed)
  - Donor Deferrals (permanent and timed)

Blood Samples

- Register a blood sample
- When a blood sample is registered the system will automatically create a set of tests for the sample that become part of the product release criteria.
- These tests can be linked to the laboratory so that the results are input straight from the analysers therefore no need for manual entry of results. (Good Quality Practice)

Harvest event period

- One harvest event covers a 9 month period.
- One blood sample covers the harvest event period
- Consent process recorded.
- Gestational age recorded.

Product registration

- The system links all the recorded products to the respective donor (mother)
- All delivered milk products can be entered at the one sitting.
- System records freezer that the product will be stored in.
- Expiry dates are automatically calculated for each product
- The weights of each product are input and the system automatically calculates the volume.
- All Barcodes produced are verified to ensure quality of the label print.

Pooling and Splitting

Pooling

- Pooling milk products from one donor.
- Each product is entered into the pool separately
- Expiry date is system calculated from the oldest product in the pool
- Batch label to identify the pool is created by the system.
- All barcodes produced are verified
- Ability to select a post pasteurisation test (if required)

Splitting

- Registration of all splits produced from pool
- System generates unique product labels for the desired number of splits. (user defined in process)
- All Barcodes are verified
- Each split can have the same or differing volumes.

Pasteurisation

- Allows for batches from more than one donor to be pasteurised together (if preferred)
- Pasteurisation date, pasteurizer identifier and batch number recorded
- Block freezer allocation
- Any product recorded in this process is linked to the batch(es) and the result of any failure within the process will be applied to all batches within this process. (products from these batches will require to be discarded)

Acceptance & Final labelling

- Checks all tests meet requirements. E.g. HIV
- Checks for donor deferrals
- Checks for Bacteriology tests from pasteurisation process.

Test result input

- Automated through connection to Blood Authority Laboratories. (Uses LIMS)
- Manual entry of results will be done by a double blind input method (GMP)

Acceptance

- Final pre labelling checking of product status and test results.
- Creation where appropriate of final product label to facilitate issue.
- Allows products to be recorded as moved into issue freezer(s)
- Failed acceptance

Issue

- All tests and deferrals rechecked by the system automatically to ensure safety.
- Can do an issue to bulk distribution or specified patient (baby) (can be done retrospectively)
- Recording of recipient and usage detail if required.
- If patient issue, system allows for hospital , ward etc to be recorded.
- Issue report system produced.

Issue (outside normal process)

- Specially designed labels to allow non users of the system to do product issues outside normal practice. (Labels have tear-offs)
- Use of these special labels reduces the risk of poor transcription of important information during this type of issue.
- Allows retrospective issue by milk bank staff at the next available opportunity.
- Facilitates accurate stock control

Confirmed Issue

- Confirms recipient usage by split.
- Allows recipient or usage to be added / edited.
- Reports from system will provide details of products with no final fate.

Reports

- Various reports exist on system, including:-
  - Confirmation of usage
  - Discard statistics
  - Usage statistics
  - Stock reports (WIP, what's in stock, what stock is nearing expiry)

Enquiries

- Unique enquiry facility

Mother to own baby portable device

- Being Developed to provide a safe method of giving mothers own milk to her own baby(s).
- Accommodates multiple births.
- Provides confirmation of use label
- Provides all applicable labels

Ensuring the 5 Patient Rights

The *right* product

The *right* route

The *right* dose

The *right* time

The *right* patient

Quality Summary

- Use of Industry standard coding.
- Electronic test result update where available.
- Electronic issue acceptance and issue checking.
- Process control.
- Full audit from donor to recipient.
- Confirmed Usage of products
- All Barcode labels produced are quality checked.
- Secure login process.
- Full journal of user activity.