



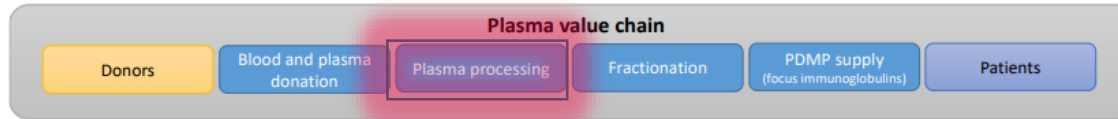
Work Package 3 Plasma Collection and Processing Best Practices

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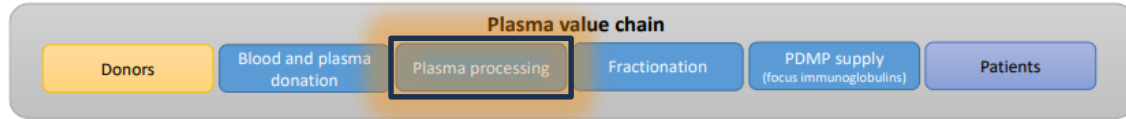
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Participants

WP 3 team:

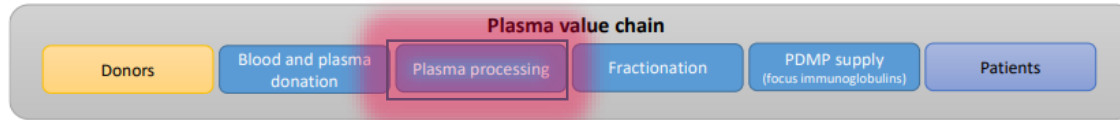
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WP3: Plasma Collection and Processing Best Practices

WP objective:

- Develop a set of recommendations that will support increased and improved plasma collection programmes by BEs throughout Europe and will ultimately strengthen the resilience of plasma collection during crisis.



WP3 TASKS

Task 3.1: Identify the most suitable approach to start a new donor center or expand an existing donor center

Task 3.2: Improving the plasma collection & processing chain

Task 3.3: Characterization of the waste of recovered plasma and lost opportunities for plasmapheresis in European Union

Task 3.4: Plasma price & cost modelling

Task 3.5: Quality of collected plasma

Methods:

1. Meetings via Teams
2. Visit Blood Establishments in Denmark and Scotland
3. Workshops on plasma journey set up
4. Analyses and discussion on cost modelling
5. Survey
6. Reports



TASK 3.1.

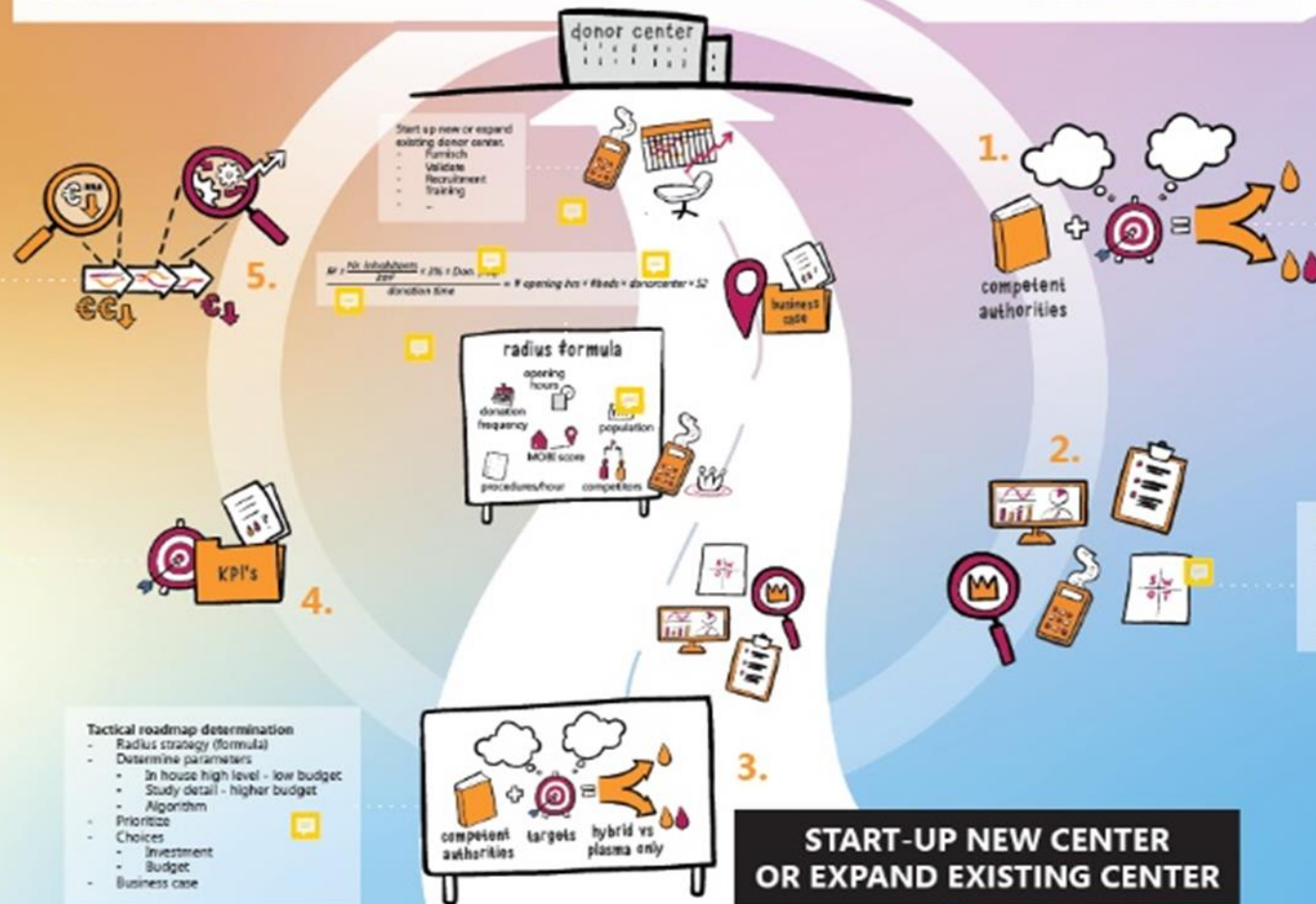
Identify the most suitable approach for BE's to start a new donor center or increase their collection programs



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START PDCA CYCLE

OPTIMIZE PROCESS



Evolution of costs

- New national and international insights
- Adjusting
- Levelling
- Impact strategic
- year plan

Define KPI for monitoring operational performance

- Budget
- Target
- Continuous improvements

Tactical roadmap determination

- Radius strategy (formula)
- Determine parameters
 - In house high level - low budget
 - Study detail - higher budget
- Algorithm
- Prioritize
- Choices
 - Investment
 - Budget
- Business case

Strategic principles determine need/question

- From government and/or competent authorities
- Other agencies
- Legal requirements
 - National
 - International
- Market position

Strategy decisions - input SWOT

- Target
- Potential
- Donor
- Target group
- Demographics
- Geographical spread
- Data mining - analysis

**START-UP NEW CENTER
OR EXPAND EXISTING CENTER**



Recommendations

Identify the most suitable approach to start a new donor center or an expand existing donor center

1. **Recommendation for a step by step plan**

- Use a proven methodology for continuous improvement and decision making such as the PDCA cycle. .
- Use SWOT analysis for plasma donor definition, target population, demographics, and geographic distribution

2. **Recommendation to determine the need for and location of new donor centres**

- Use a systematic approach to determine the optimal number of donor centers and their strategic location
- Use the RADIUS formula where a set of parameters are designed implementing more technical site selection methods.

3. **Recommendation on the use of more technical location selection methods**

- For more technical methods (donor demographics) it is advisable to work with specialized companies or universities.

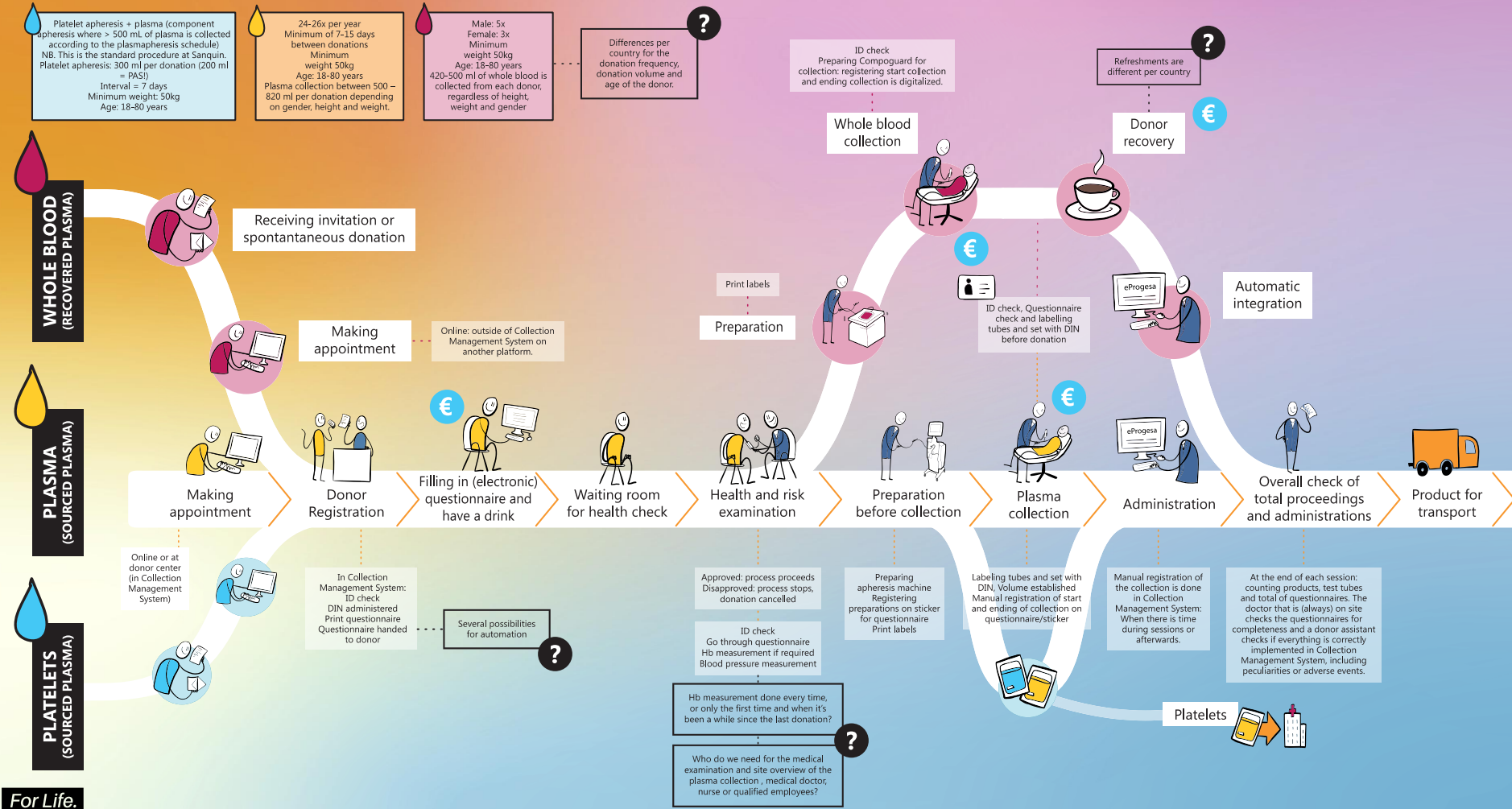


TASK 3.2.
Improving the plasma collection & processing chain

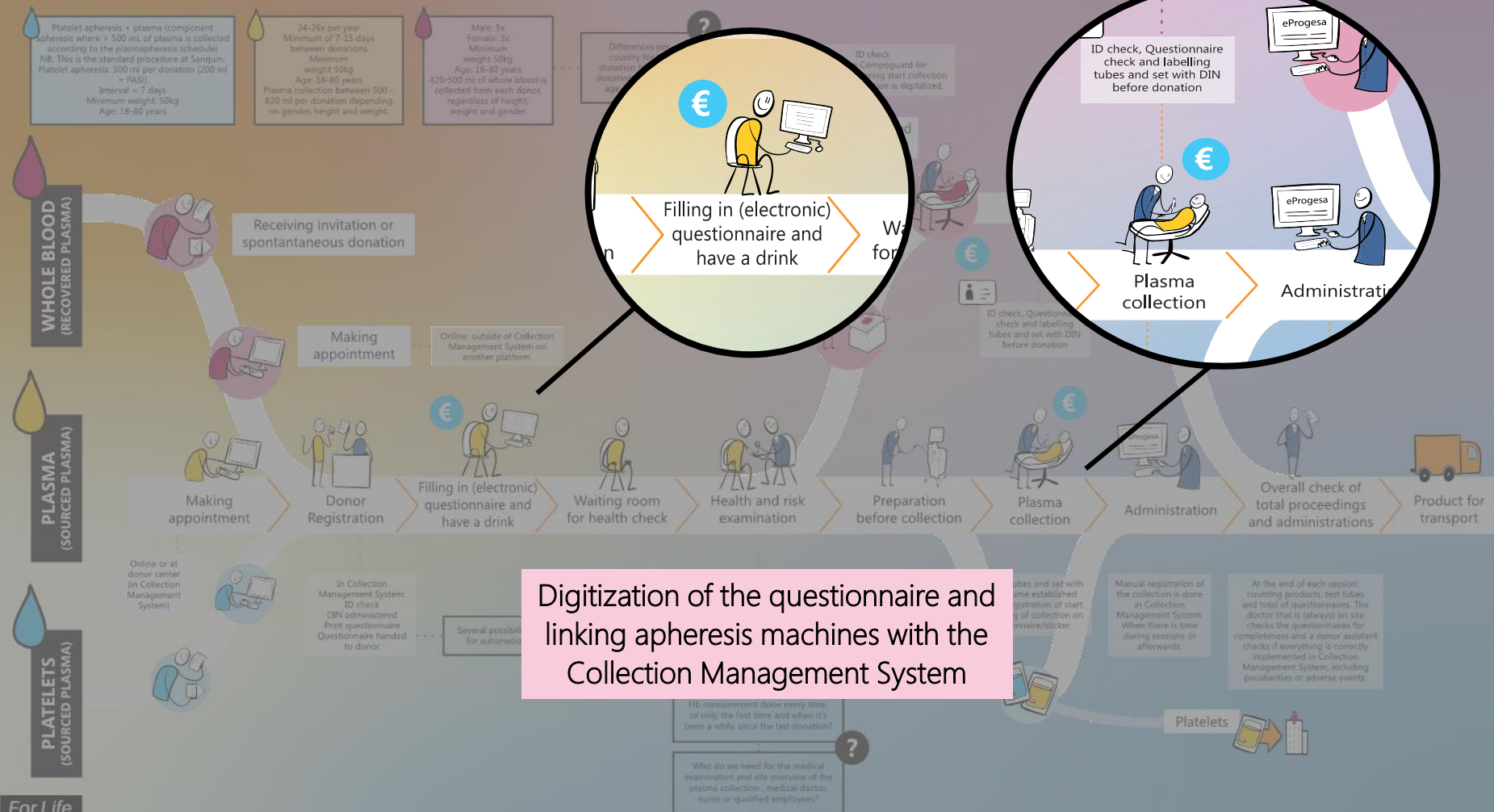


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COLLECTION PHASE

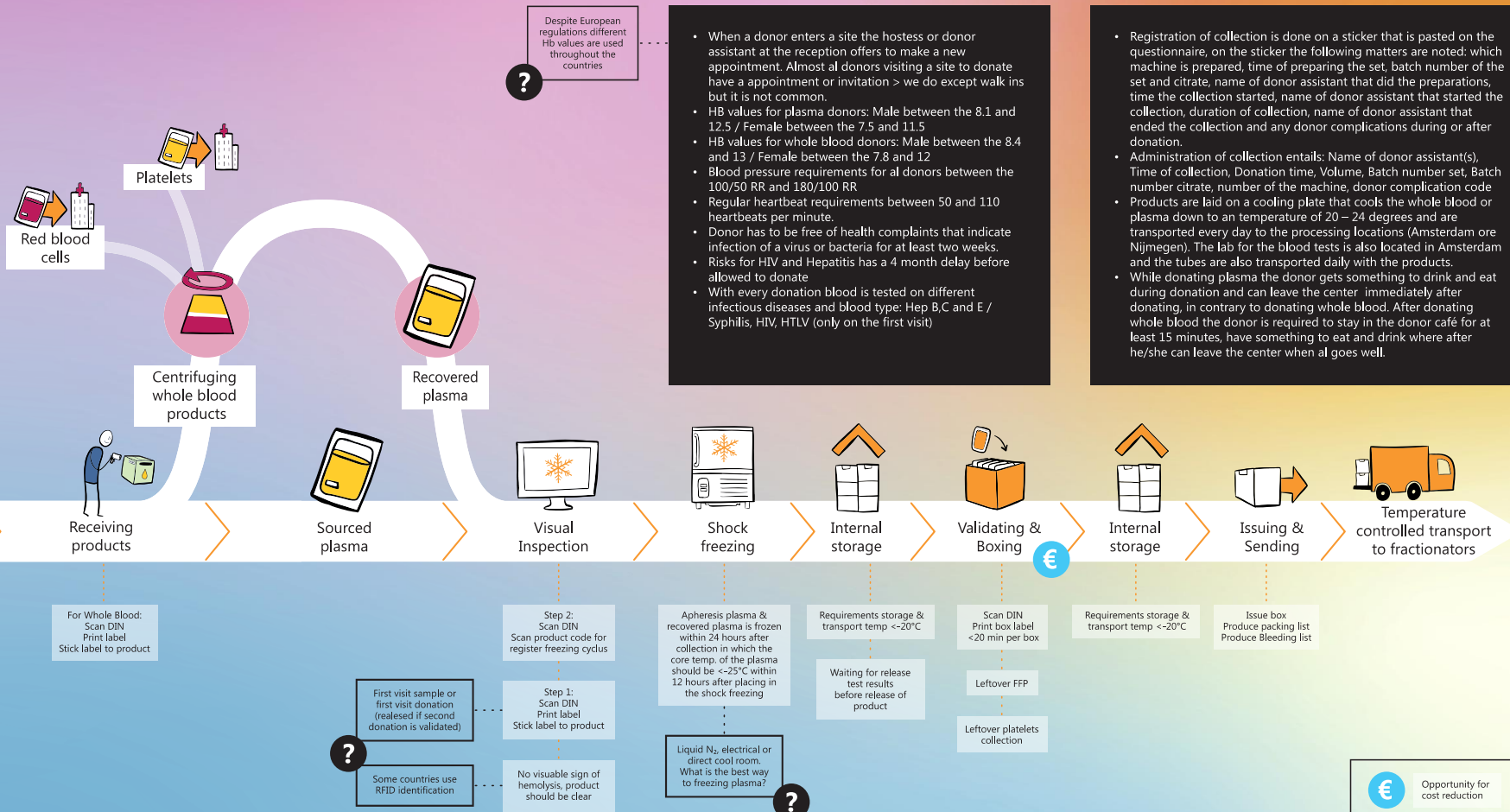


COLLECTION PHASE



PROCESSING & TRANSPORT PHASE

EXTRA INFORMATION



Despite European regulations different Hb values are used throughout the countries

- When a donor enters a site the hostess or donor assistant at the reception offers to make a new appointment. Almost all donors visiting a site to donate have a appointment or invitation > we do except walk ins but it is not common.
- HB values for plasma donors: Male between the 8.1 and 12.5 / Female between the 7.5 and 11.5
- HB values for whole blood donors: Male between the 8.4 and 13 / Female between the 7.8 and 12
- Blood pressure requirements for al donors between the 100/50 RR and 180/100 RR
- Regular heartbeat requirements between 50 and 110 heartbeats per minute.
- Donor has to be free of health complaints that indicate infection of a virus or bacteria for at least two weeks.
- Risks for HIV and Hepatitis has a 4 month delay before allowed to donate
- With every donation blood is tested on different infectious diseases and blood type: Hep B,C and E / Syphilis, HIV, HTLV (only on the first visit)

- Registration of collection is done on a sticker that is pasted on the questionnaire, on the sticker the following matters are noted: which machine is prepared, time of preparing the set, batch number of the set and citrate, name of donor assistant that did the preparations, time the collection started, name of donor assistant that started the collection, duration of collection, name of donor assistant that ended the collection and any donor complications during or after donation.
- Administration of collection entails: Name of donor assistant(s), Time of collection, Donation time, Volume, Batch number set, Batch number citrate, number of the machine, donor complication code
- Products are laid on a cooling plate that cools the whole blood or plasma down to an temperature of 20 – 24 degrees and are transported every day to the processing locations (Amsterdam ore Nijmegen). The lab for the blood tests is also located in Amsterdam and the tubes are also transported daily with the products.
- While donating plasma the donor gets something to drink and eat during donation and can leave the center immediately after donating, in contrary to donating whole blood. After donating whole blood the donor is required to stay in the donor café for at least 15 minutes, have something to eat and drink where after he/she can leave the center when al goes well.

First visit sample or first visit donation (released if second donation is validated)

Step 1: Scan DIN
Print label
Stick label to product

Step 2: Scan DIN
Scan product code for register freezing cyclis

Liquid N₂ electrical or direct cool room. What is the best way to freezing plasma?

Waiting for release test results before release of product

Scan DIN
Print box label
<20 min per box

Leftover FFP

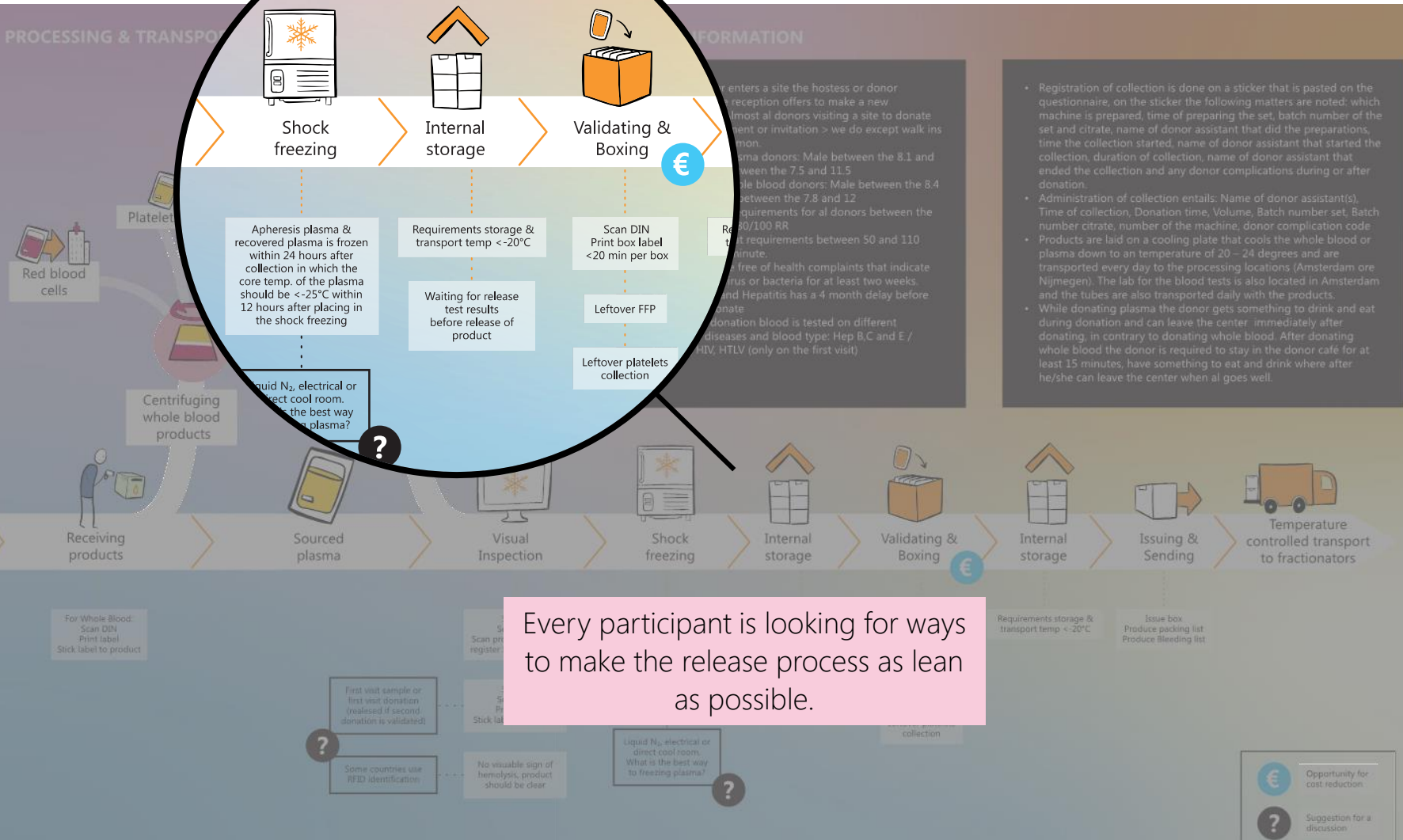
Leftover platelets collection

Requirements storage & transport temp <-20°C

Issue box
Produce packing list
Produce Bleeding list

€ Opportunity for cost reduction

? Suggestion for a discussion



Shock freezing

Internal storage

Validating & Boxing



Apheresis plasma & recovered plasma is frozen within 24 hours after collection in which the core temp. of the plasma should be <-25°C within 12 hours after placing in the shock freezing

Requirements storage & transport temp <-20°C

Waiting for release test results before release of product

Scan DIN
Print box label
<20 min per box

Leftover FFP

Leftover platelets collection

Liquid N₂, electrical or direct cool room. What is the best way to freeze plasma?



Every participant is looking for ways to make the release process as lean as possible.

- Registration of collection is done on a sticker that is pasted on the questionnaire, on the sticker the following matters are noted: which machine is prepared, time of preparing the set, batch number of the set and citrate, name of donor assistant that did the preparations, time the collection started, name of donor assistant that started the collection, duration of collection, name of donor assistant that ended the collection and any donor complications during or after donation.
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For Whole Blood:
Scan DIN
Print label
Stick label to product

First visit sample or first visit donation (released if second donation is validated)



Some countries use RFID identification

No visible sign of hemolysis, product should be clear

Liquid N₂, electrical or direct cool rooms. What is the best way to freezing plasma?



Requirements storage & transport temp <-20°C

Issue box list
Produce bleeding list



Opportunity for cost-reduction



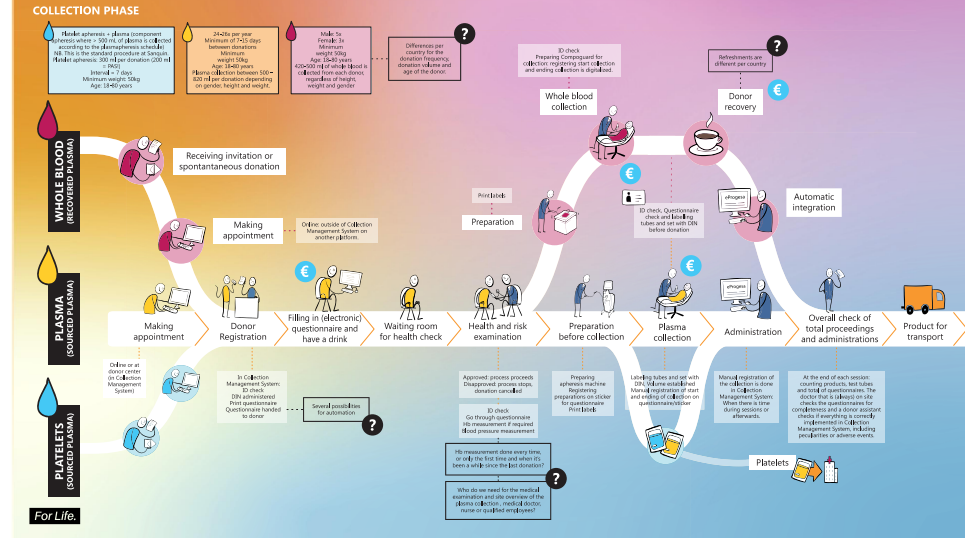
Suggestion for a discussion



Recommendations

Plasma process

- Automate and digital processes.
- Ensure the EDQM Guideline is interpreted the same way in all European Blood Establishments
- For apheresis plasma, only perform necessary viral tests: Hep B and C, Syphilis, HIV and HTLV
- Ferritin measurements should be limited to whole blood donation and not introduced in plasma apheresis
- Further research is needed on necessity of Hb or blood pressure measurement
- Plasma donation volumes should be measured in litres instead of kilos





TASK 3.4.
Plasma price & cost modelling

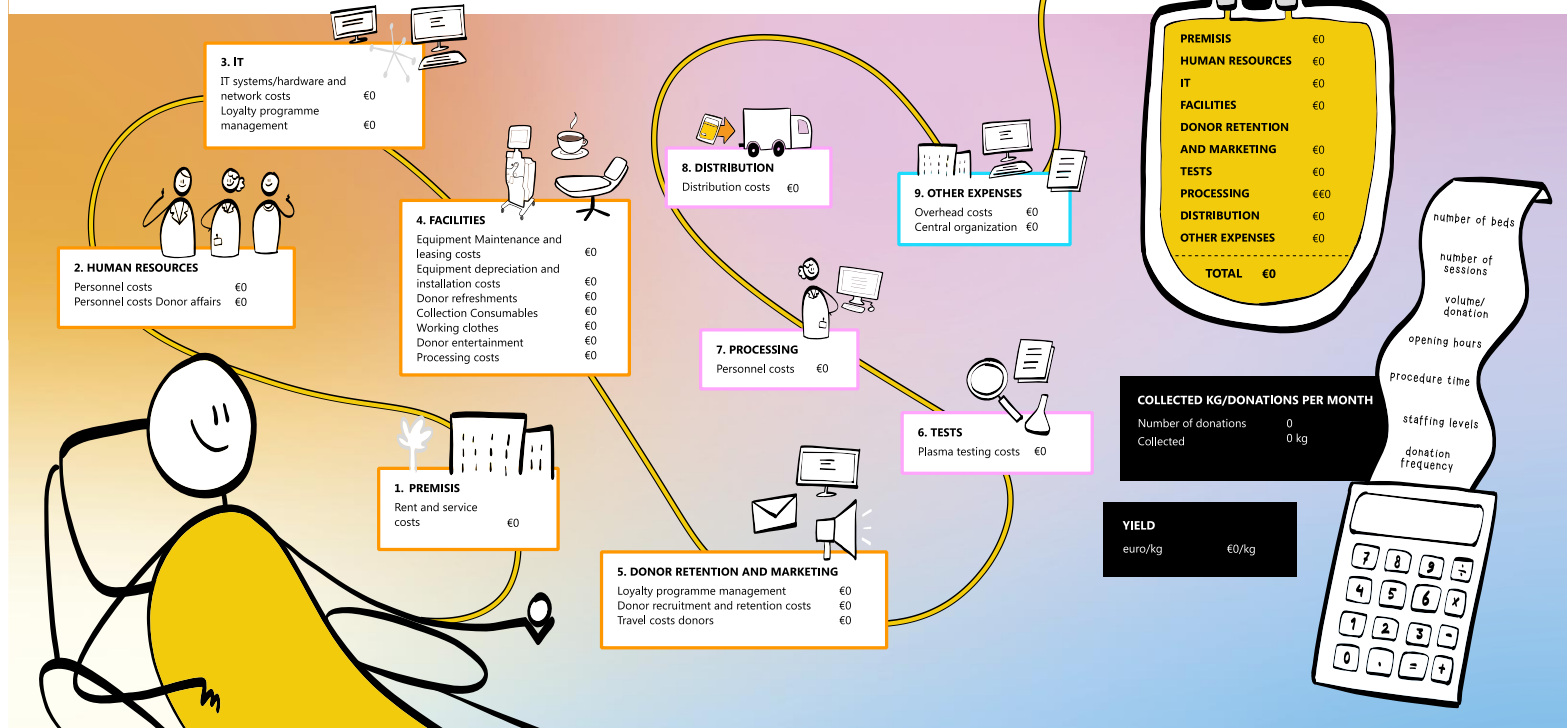


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Cost modelling

In collection and processing

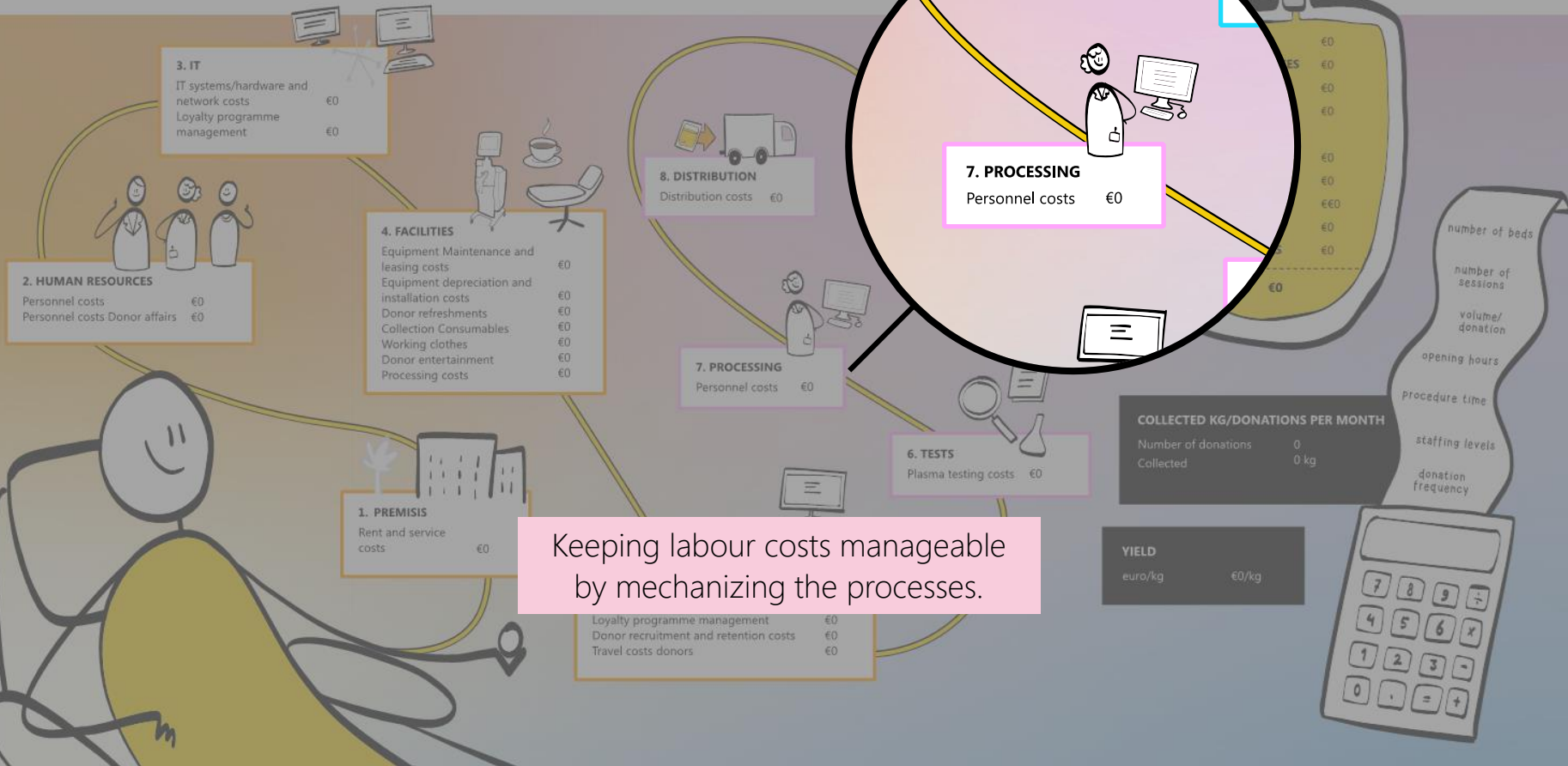
■ COLLECTION
■ PROCESSING AND DISTRIBUTION
■ SEVERAL



Cost modelling

In collection and processing

- COLLECTION
- PROCESSING AND DISTRIBUTION
- SEVERAL



Keeping labour costs manageable by mechanizing the processes.



Recommendations

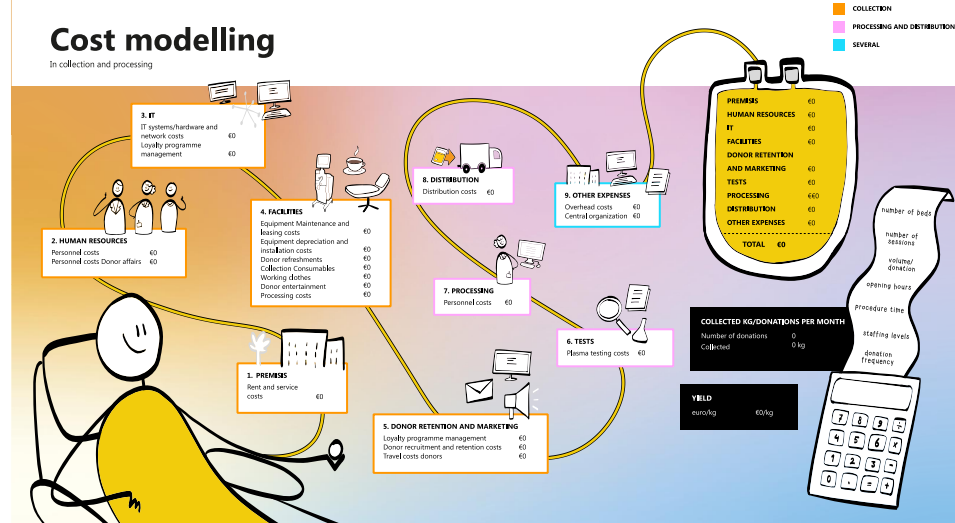
Cost model

The costs of apheresis programs are currently too high. Therefore, the recommendation is to implement the following efficiency measures:

- Focus on retaining donors and increasing donation frequency while also recruiting more donors;
- Invest in automation of the processes;
- Eliminate all unnecessary (medical) actions that are necessary for the collection of whole blood but are not strictly necessary for the collection of plasma;
- Strengthen the negotiation position to increase revenues.

Cost modelling

In collection and processing

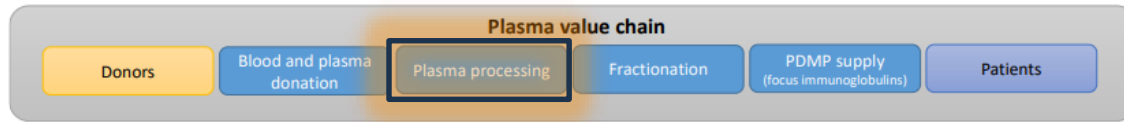




Take aways

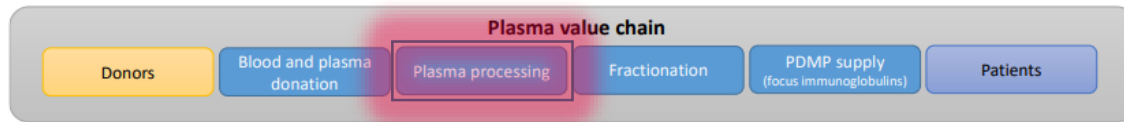


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Task 3.1 Identify the most suitable approach for BE's to start or increase their collection programs and assist BE's with decision making

- Use a business case with the national goals/targets, and set the course with the steps of design, validation, recruitment, training, and advertising.
- By defining operational KPI's and jointly monitoring cost development, analysts can effectively navigate the donor center management.



Task 3.2 Improving the plasma collection & processing chain

- Ensure the EDQM Guideline is interpreted the same way in all European Blood Establishments
- For apheresis plasma, only perform necessary viral tests: Hep B and C, Syphilis, HIV and HTLV
- Further research is needed on necessity of Hb or blood pressure measurement

Task 3.4 Plasma price & cost modeling

- Focus on retaining donors and increasing donation frequency while also recruiting more donors
- Invest in automation of the processes
- Eliminate all unnecessary (medical) actions that are necessary for the collection of whole blood but are not strictly necessary for the collection of plasma
- Strengthen the negotiation position to increase revenues



Next steps

Let's learn from each other

Refining the cost model and discussing the differences in costs with a number of European countries.

Invest in efficiency measures of the plasma collection and processing chain to reduce the costs and increase the volumes of plasma collected.



SUPPLY Project

Strengthening voluntary non-remunerated plasma collection capacity in Europe

OUR PARTNERS

ABOUT US

What is SUPPLY?

SUPPLY is a project co-funded by the European Union's EU4Health Programme that aims to increase and strengthen the resilience of plasma collection in the EU to enable a stable and adequate supply of Plasma-derived medicinal products (PDMPs). The entire plasma chain is



SUPPLY

Thank You

Questions / Comments/ More Information :

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