

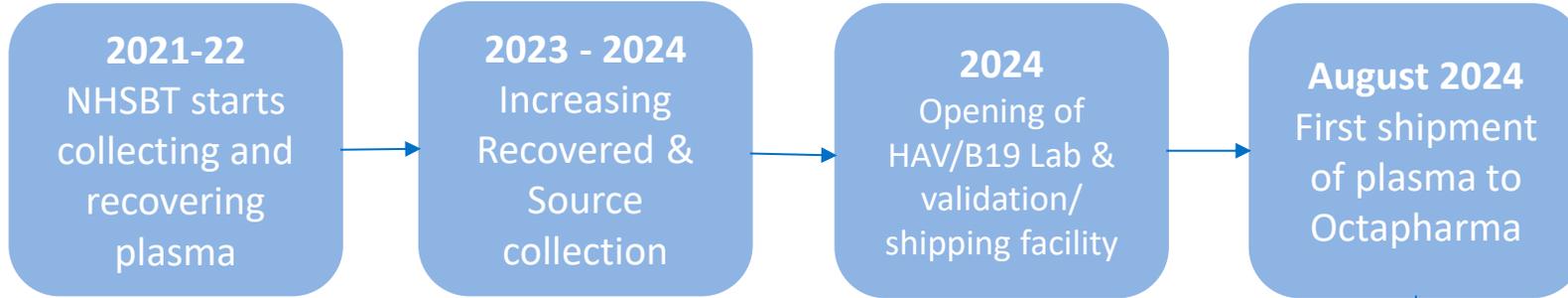
**Our journey to
self-sufficiency...**

**...three years in
the making**

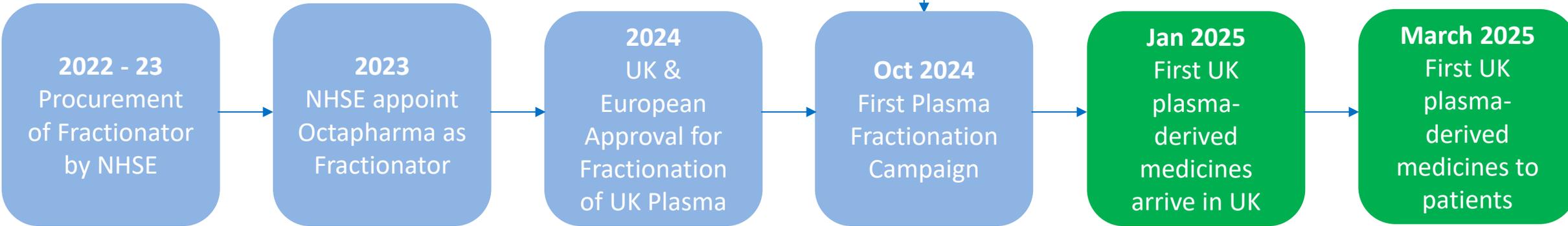


Our journey so far...

Collection



Fractionation



By the end of 2025 we aim to have:

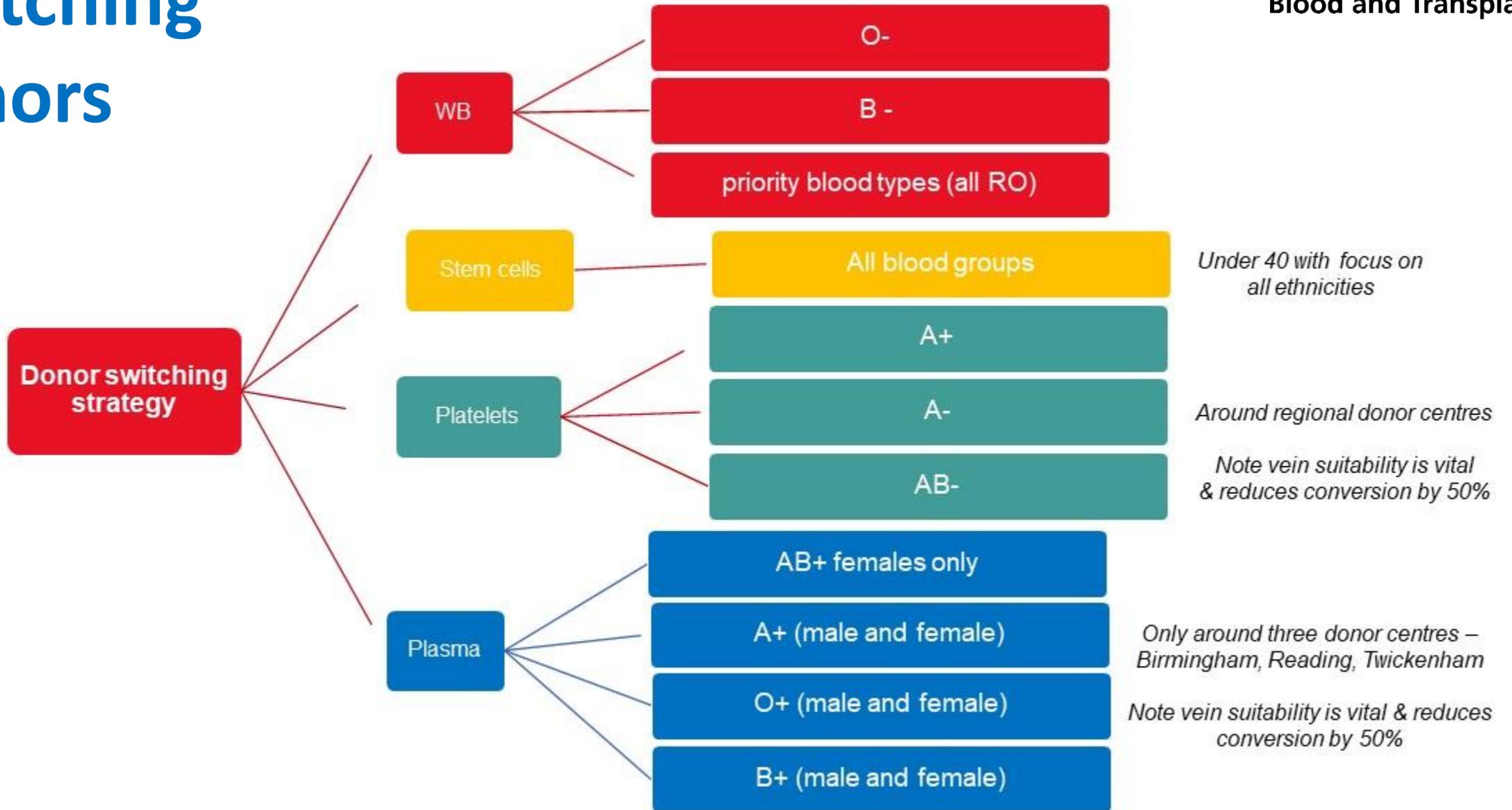
- delivered a stable end-to-end medicinal supply chain, with licensed IVIg and Albumin products to UK patients
- maximised the recovery of plasma from whole blood donations
- demonstrated source plasma collection (c10,000L @ centre) at scale
- started to increase source plasma footprint



***All types can
save lives***

Building our plasma donor base

Switching donors



Influencing behaviour?

1



Pin badge
(New donors only)

2



Phone holder
Keyring

4



Shopping bag

6



Choice of socks
or gym towel

12



Water bottle



travel

Collecting plasma



Multi Product Centre



A multi-product Centre (Plasma, WB and Platelet) creates the opportunity to learn how new donors can be encouraged to donate different products.



Birmingham

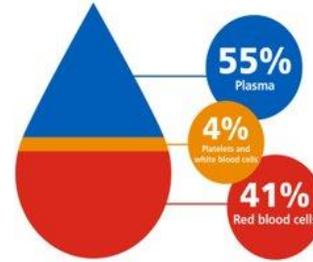
Reading

Twickenham

Plasma Only Centre



Test the operations of a dedicated Plasma only centre.
Learning how to drive donation frequency from a prioritised plasma donor geographical base. (maintaining high priority WB groups for WB collections)



- 24 fixed Whole Blood donor centres
- 48 mobile Whole Blood donor teams
- ★ Manufacturing sites



Hybrid Collection

Test the concept of a co-located site between WB and Plasma with a single Plasma led governance



First NHS patients 'in a generation' get plasma from UK donors



NEWS

First patients get UK-sourced plasma in generation



NEWS

Patients thank blood donors for life-saving plasma





***All types can
save lives***

Building our Supply Chain

Plasma Portfolio



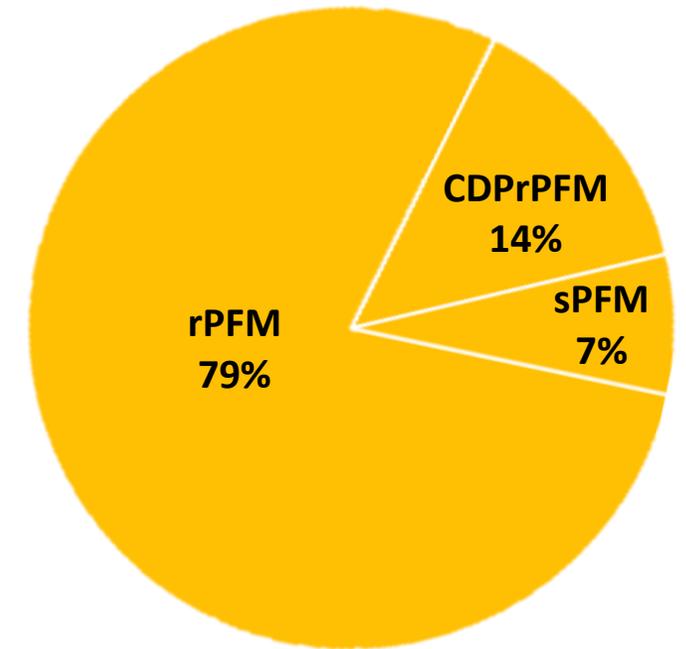
- recovered from approx. 1m Whole Blood donations per year
- mean volume 275ml
- all female plasma
- male plasma not required for FFP



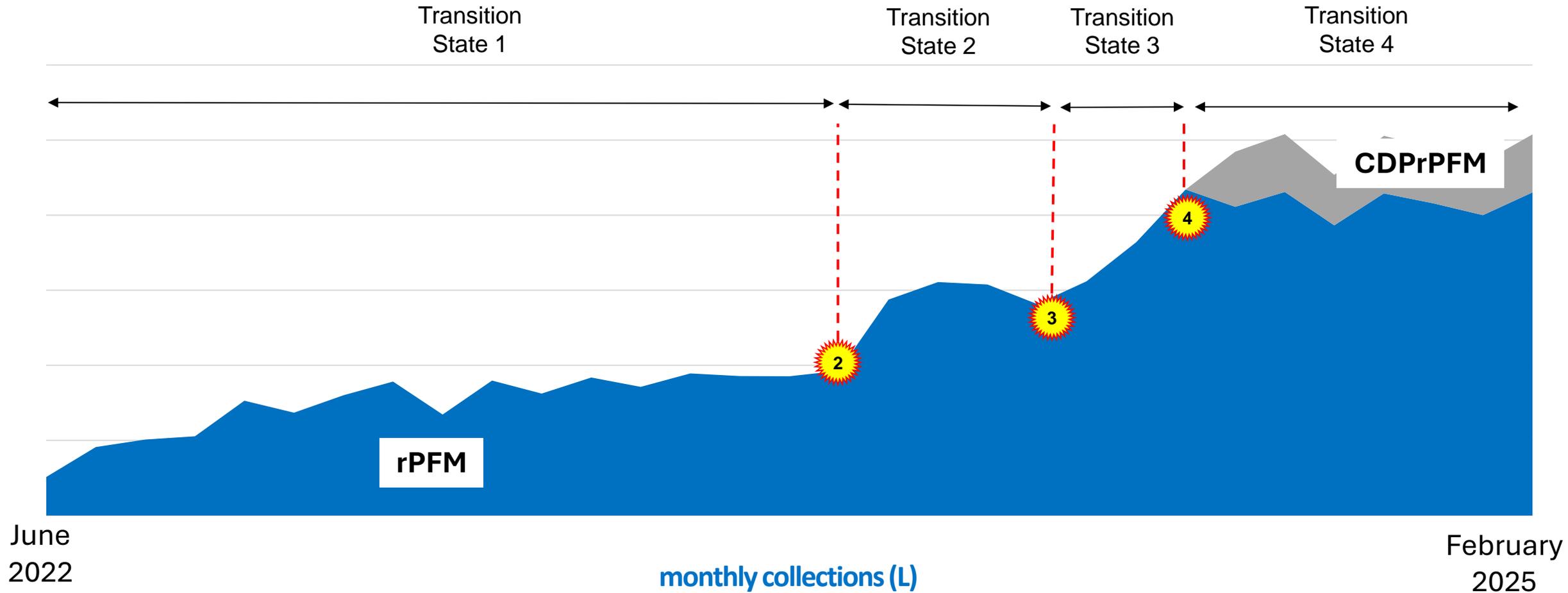
- part of the rPFM “family”
- by-product of cryoprecipitate blood component manufacture
- mean volume 220ml
- male plasma only



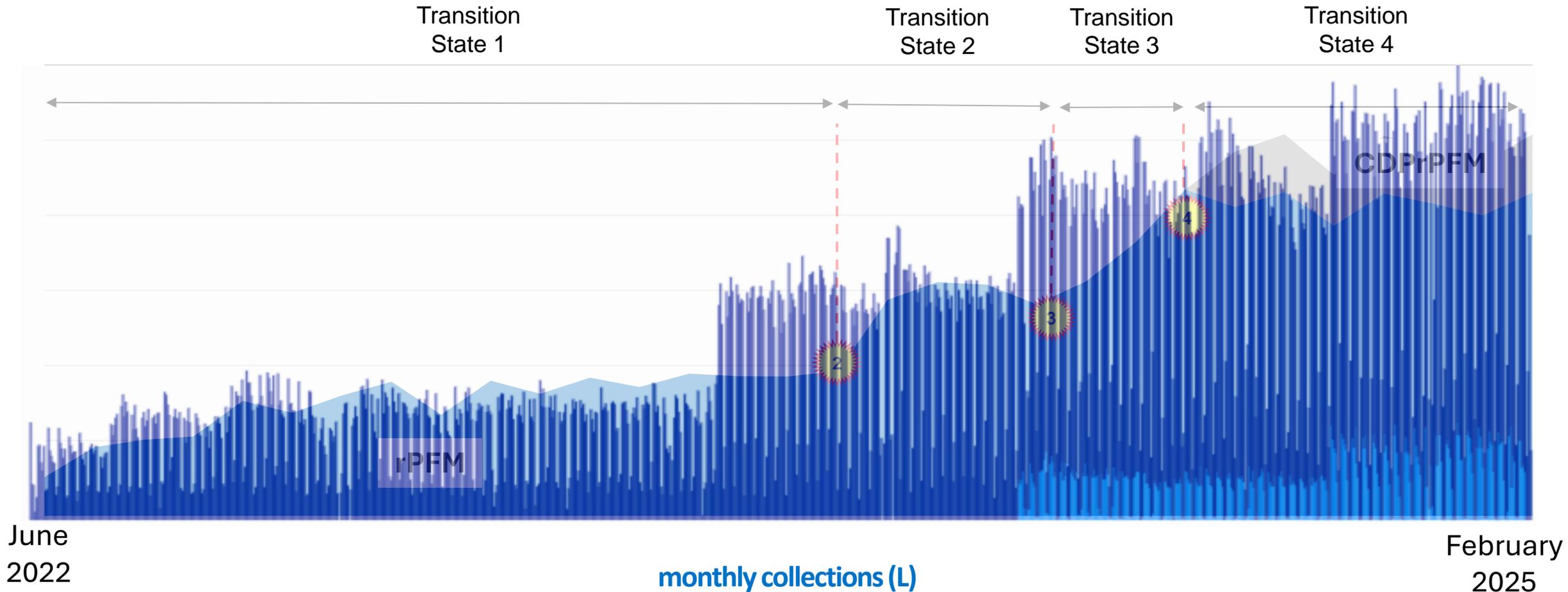
- mean volume 625ml
- female and male female plasma



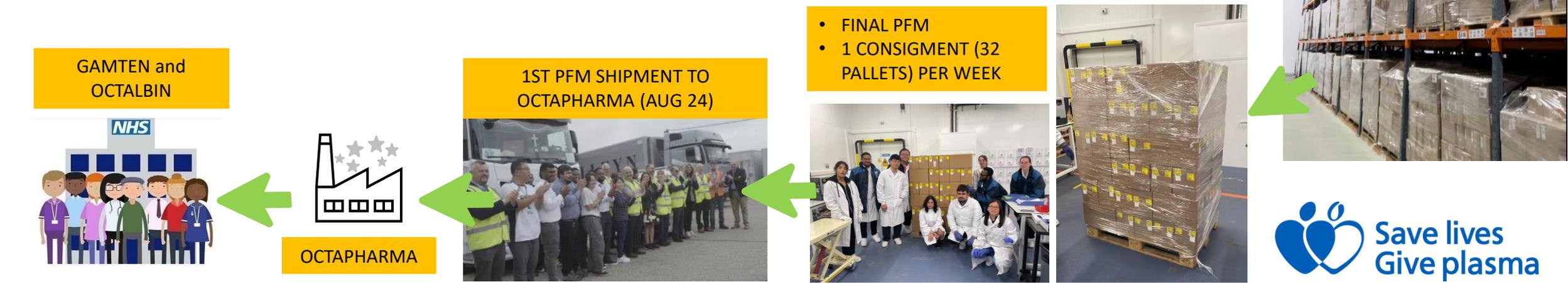
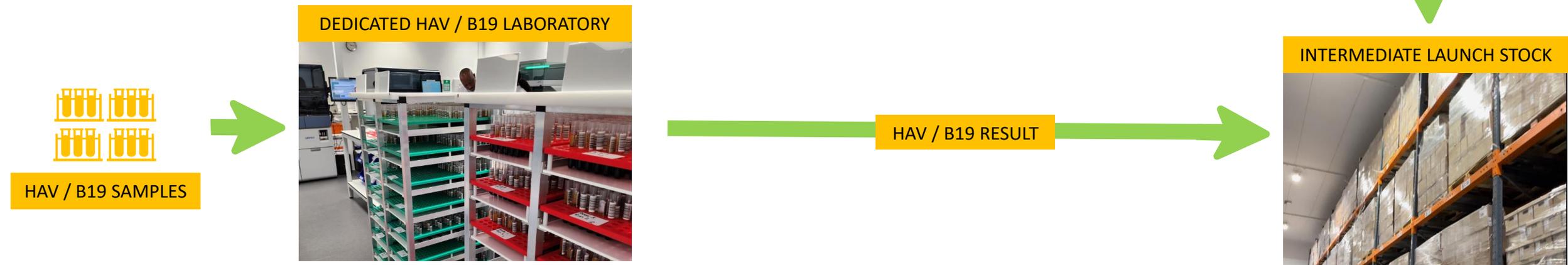
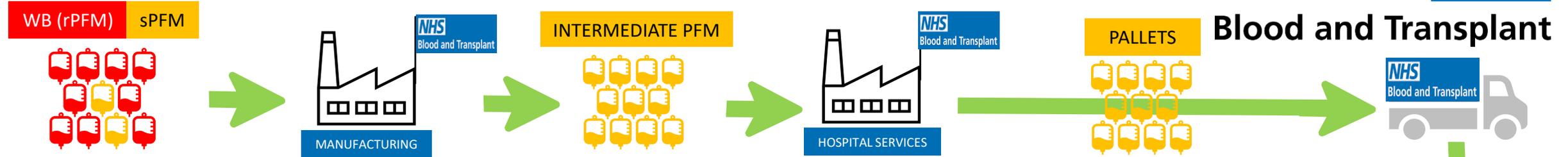
rPFM – plan



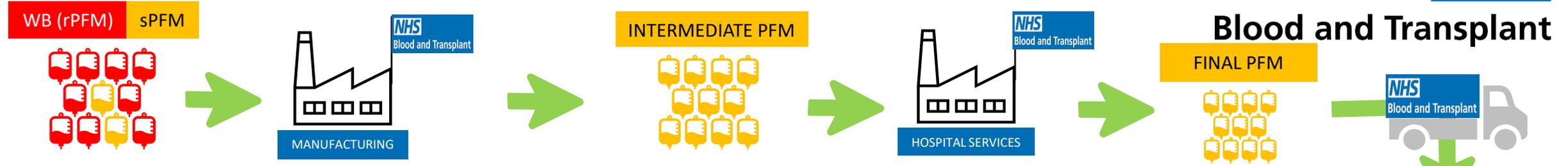
rPFM – actual vs plan



Optimising our supply chain (1)



Optimising our supply chain (2)



Where next...



Self-sufficiency targets

- In 2025 we will achieve 25% (IVIg) / 80% (albumin) self-sufficiency
- Currently modelling for ambition (35% self-sufficiency)



Collections - additional 1% self-sufficiency from:

- Maximising collections / improved operating model
- New donor centre footprint strategy
- Explore multi-product donor centres



Supply Chain – improving efficiency

- Optimisation? Automation? Value streams?
Standardisation? RFID??
- Learn from others



Thank you

Questions....?



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Tiffany Jones
Assistant Director, Plasma Marketing
& Communications
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Self-sufficiency of plasma with VNRD

The Danish journey

EDQM STAKEHOLDER EVENT - PLASMA SUPPLY
CONTINUITY

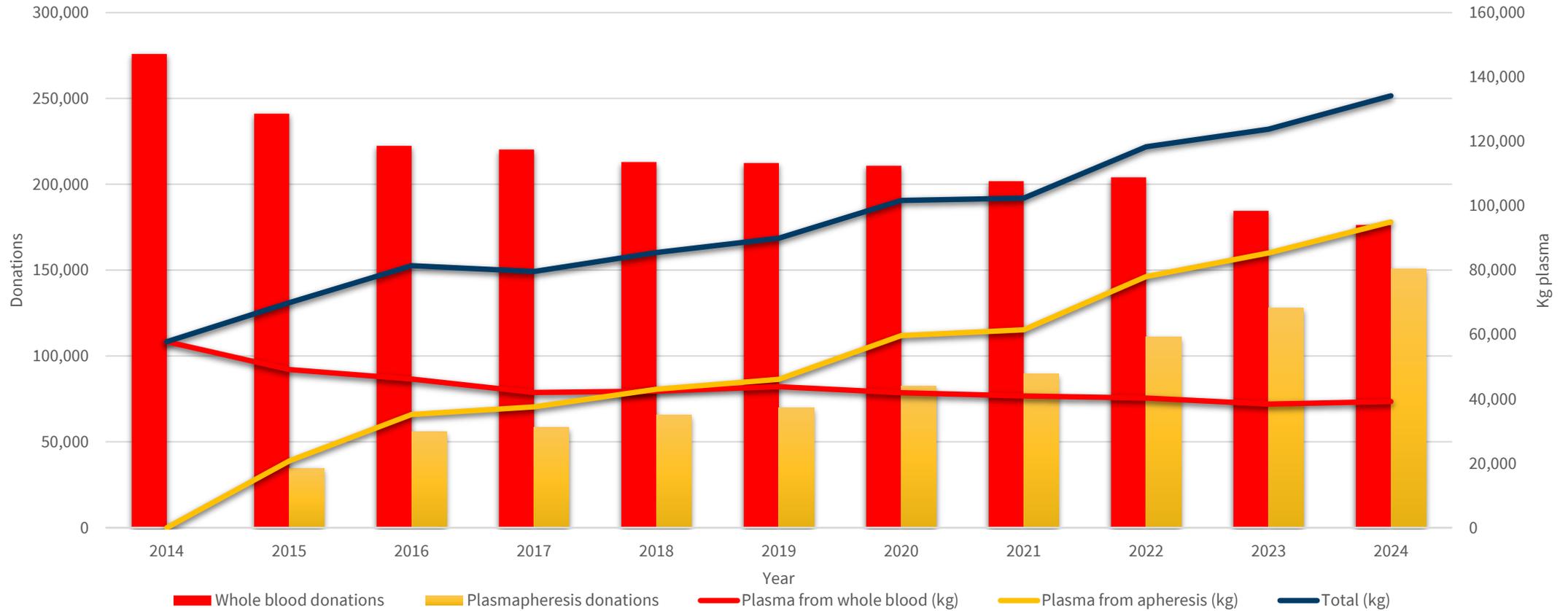


European Committee
(Partial Agreement)
on Blood Transfusion
(CD-P-TS)

EDQM
21st Edition
2023

Status on collection of plasma for fractionation

Plasma for fractionation - Denmark



Background

Legislation - National act on blood

- §1 blood donors cannot be remunerated or compensated
- §3 blood can only be drawn by blood banks in the public health system – incl. plasma

Organisation - 5 regional blood centres

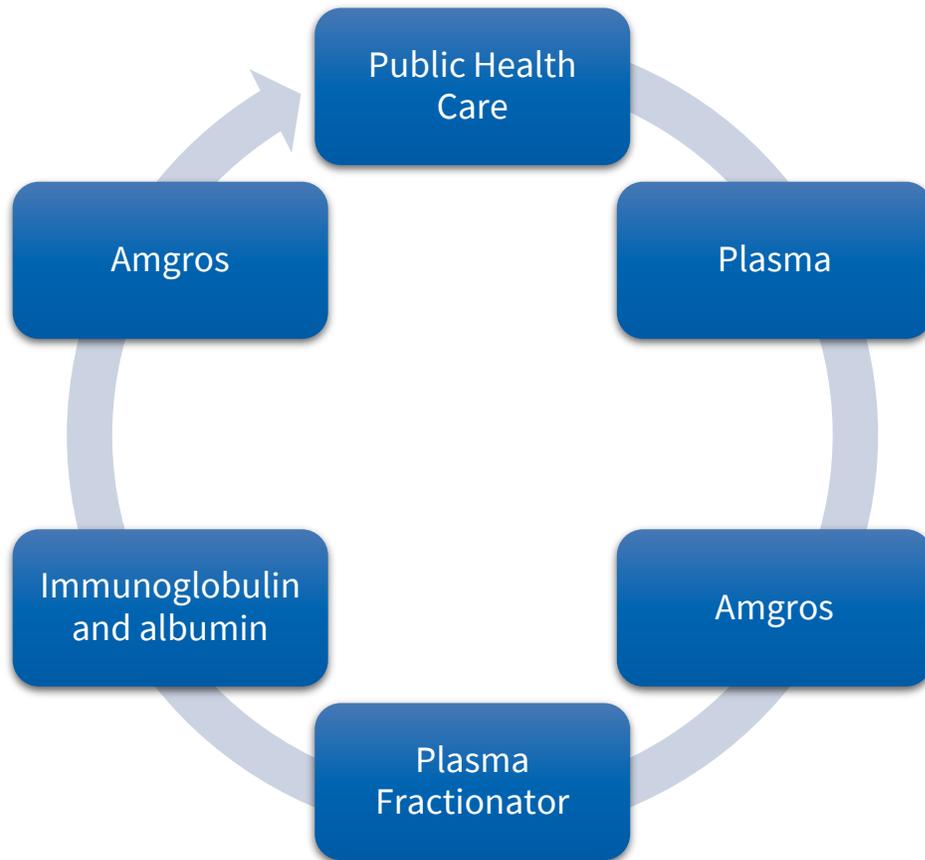
- Public based health care system
- Five regions responsible for health care of its citizens, including medicine and blood components
- Each region has their own blood centre
- A blood center consists of
 - Multiple blood banks and blood depots spread all around the region
 - One regional blood processing and testing facility
 - Laboratory facilities (immunohematology and immunology)
- Organized similar in all regions, have identical equipment, labelling system,

Background

Blood donors

- Approximately 180,000 registered blood donors, corresponding to 3.7 % of the adult population
- All donors are organized by a single donor association, Bloddonorerne Danmark
- Responsible for recruiting donors
- Donors are recruited as blood donors, not whole blood or plasma donors

Background - Contract with fractionator



Amgros

- A public company, an incorporation with 5 shareholders; one for each of the Danish regions.
- Purchases all the medicines required for all the regions
- Negotiate the plasma fractioning tenders from the public licitation

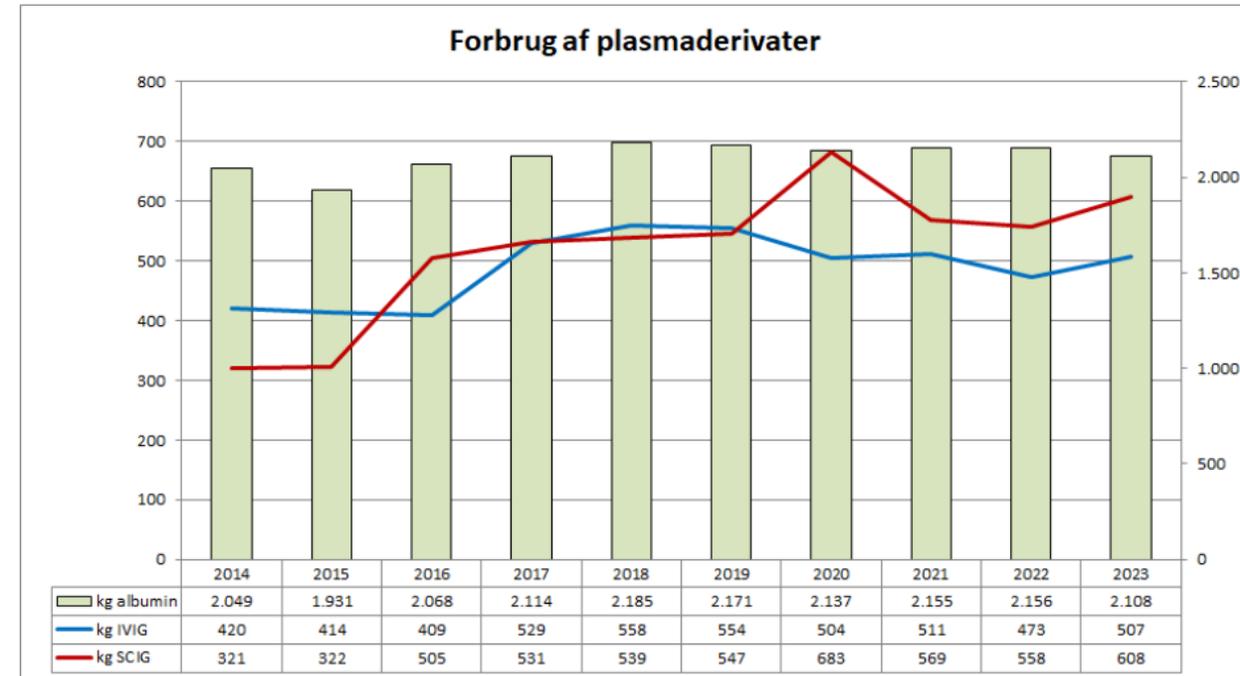
Plasma for fractionation - Goal

- Goal
- Self-sufficiency of immunoglobulins



Use of plasma derivatives in Denmark

- Denmark has a high use of immunoglobulin – and it is increasing
- The goal is ambitious, but necessary



Strategy

Political decision

Financial backup

Recruitment of donors

Change of operations in the blood centres



Strategy- political decision and financial backup

Political decision from the 5 regions:

- Collaboration between the 5 regions and the blood centres
- Initiative from the 5 blood centres in 2012
- In 2012 the regions decided to financial support plasmapheresis equipment, but only for 20 tons source plasma
- In 2017 a working group from the regions and blood centres decided on a model to aim for self-sufficiency:
 - A "Burning platform" was identified and acknowledged:
 - The use of immunoglobulin in DK was much higher than the plasma collected
 - The volume of recovered plasma was reduced due to lower use of blood for transfusion

Financial backup

- In 2021 the 5 regions decided to support the establishment of plasma centres
- Size and location of plasma centers were based on:
 - Size of population in the region (potential donor population)
 - Needed amount of source plasma for being self-sufficient
 - For efficiency, a plasma center is minimum 12 beds or maximum 24 beds

Strategy – donors and recruitment

Additional 180,000 donors needed to be recruited

A statement from the national donor organisation, that they were willing to recruit this number of donors – and that it was realistic

Donor motivation

Plasma also helps patients – Danish patients are ensured important medicine

Voluntary Non-remunerated Donors (VNRD)

Donors are recruited as blood donors

Not possible to donate plasma in all blood banks

The blood centre finally decides if donor can donate plasma

Mixed centres – high flexibility, but can interfere with productivity

Possible to change donation e.g. if low stock on O neg, or travel deferral for whole blood

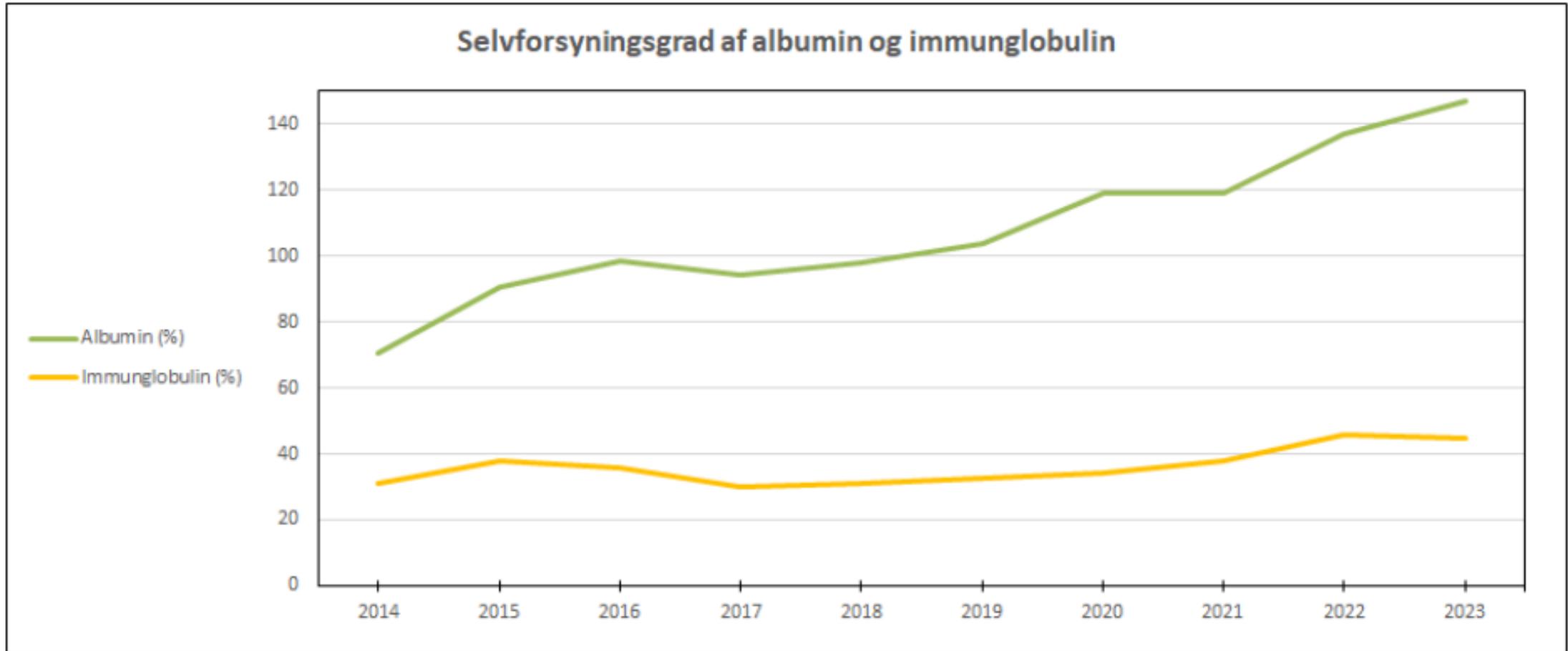


Strategy – change of operations

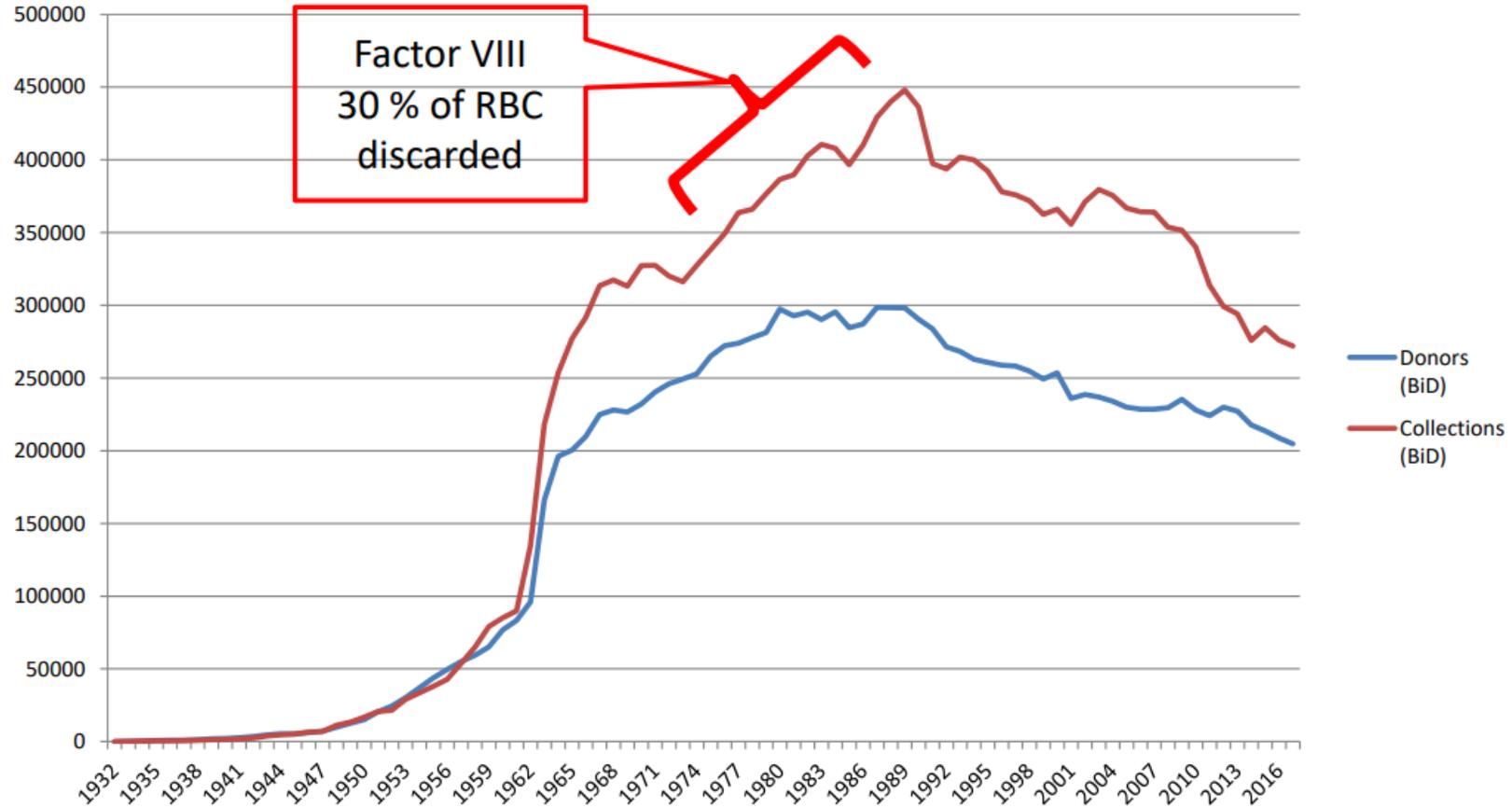
- Collection of source plasma is different from collection of whole blood
- Costs need to be reduced:
 - Productivity pr FTE can be increased
 - General level of cost can be reduced
- Procedures
 - Think ”need to have”
 - Paperless, electronic
 - Lean workflow
 - Reduce testing e.g. hemoglobin, blood grouping
 - Collection volume according to blood volume
 - Opening hours and days
- Collaborate
 - Learn from each other, national/international
 - Strategic use of high volume e.g. national tender on equipment



Goal of self-sufficiency- how are we doing?

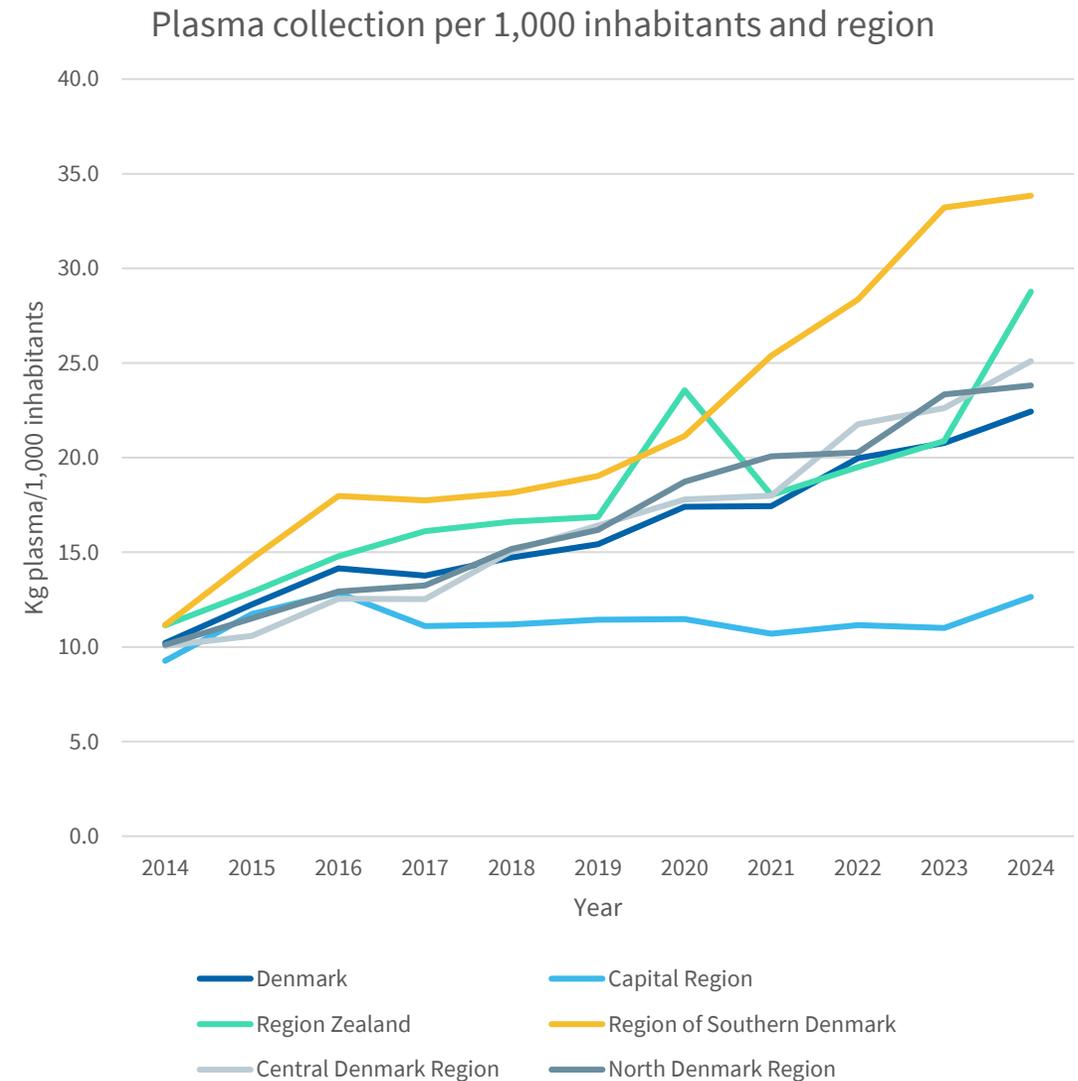


Is it a realistic goal with VNRD?



On the way to self-sufficiency

- Not all plasma centres are established
- 2020 Region of Southern Denmark and Central Denmark Region
- 2024 Region Zealand
- 2026 Central Denmark Region, North Denmark Region, Region of Southern Denmark
- 2026-27 Capital Region
- Goal is expected to be reached in 2028



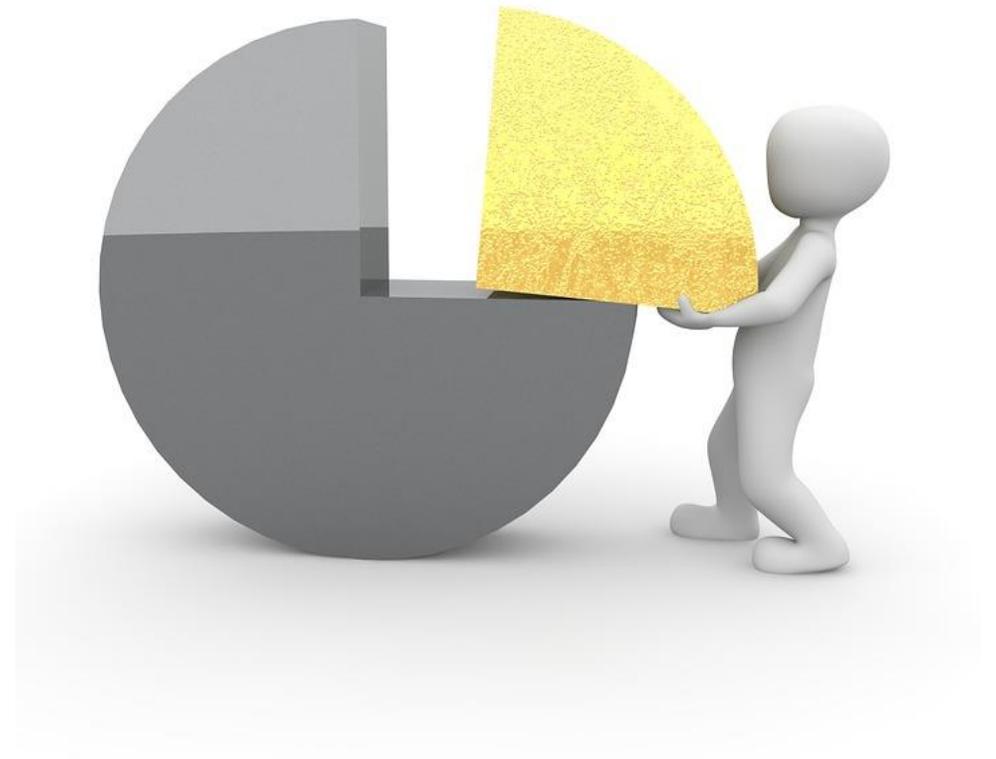
Conclusion

Self-sufficiency with VNRD still a possibility
– and proven in one region in Denmark

Overall decision and investment needed –
“burning platform” identified

Change of operations in the blood centers

Collaboration important



Thank you

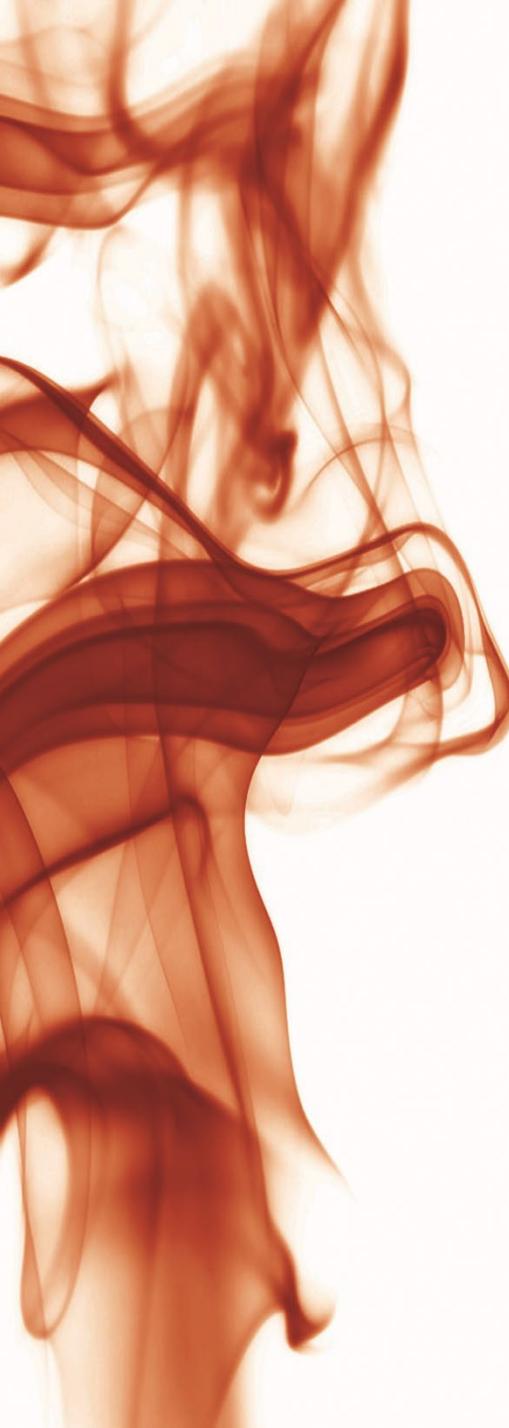
M.D., MPG, Director

Betina Samuelsen Soerensen

Dept. of Clinical Immunology

betina.soerensen@rn.dk

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Securing commitment and control for the supply of plasma derivatives for public health systems A short review

Fabio Candura

National Blood Centre

Italian National Institute of Health, Rome

Strasbourg, March 26-27, 2025

Disclosure

I do declare that I have no relevant financial or non-financial relationships within the products or services described, reviewed, evaluated or compared in this presentation other than those related to my function of Public health official.

Foreward

Sources used in preparing this presentation are taken from project “101056988/SUPPLY” co-funded from the European Union’s EU4Health Programme (2021-2027) at <https://supply-project.eu/resources/>.

In particular,

D4.2 Report on policies and/or legal frameworks in plasma collection and PDMPs management throughout EU

Results of the “Survey on plasma collection and PDMPs production from national plasma in EU”

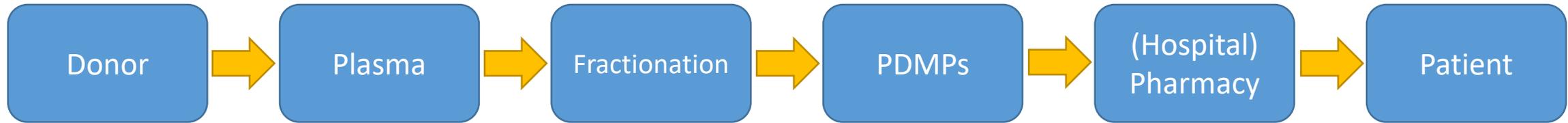
addressed to the list of national CAs for blood and blood components as provided by DG SANTE.

Background

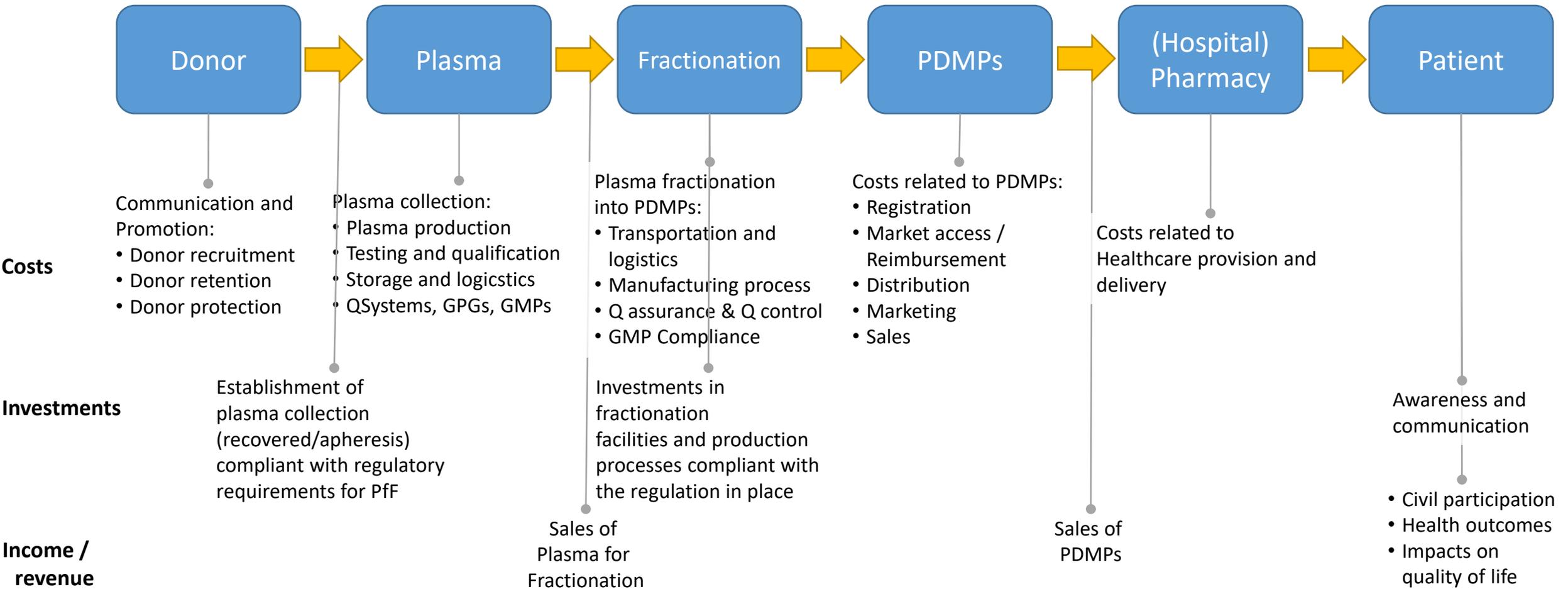
Starting from 80s - 90s

- PDMP production shifted from a public-owned to a private for-profit system and involved the collection of plasma for fractionation
- A continuous process of concentration (still in progress) of fractionators and growing of the potential manufacturing capability
- Development of non-plasma-based alternatives with consequences in the mutation of driver products:
 - from human albumin to factor VIII to immunoglobulins
 - and in the economy of production (cost structure, economy of last litre, ...)

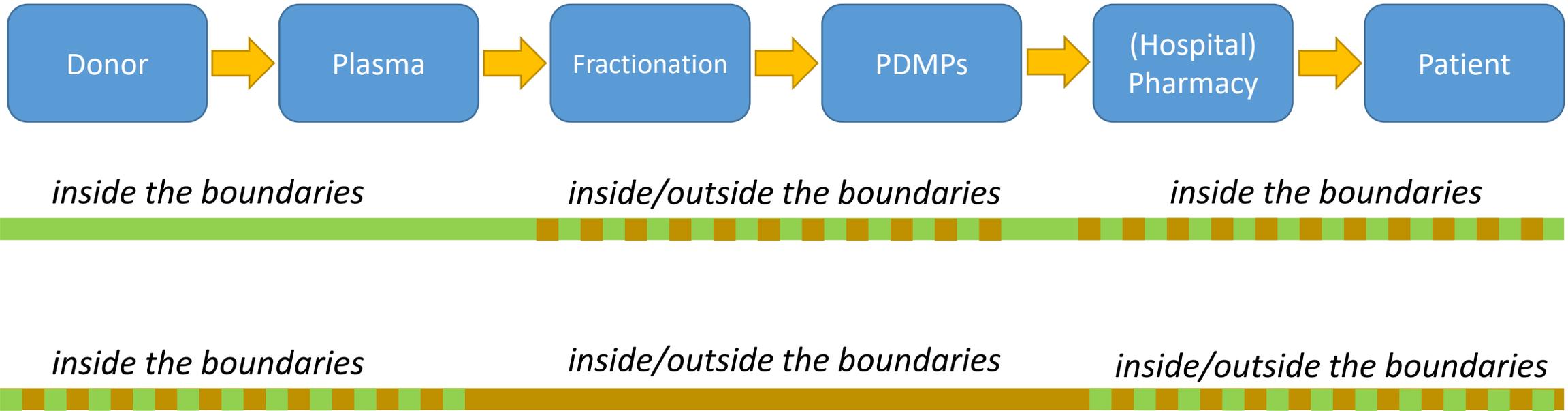
The plasma value chain



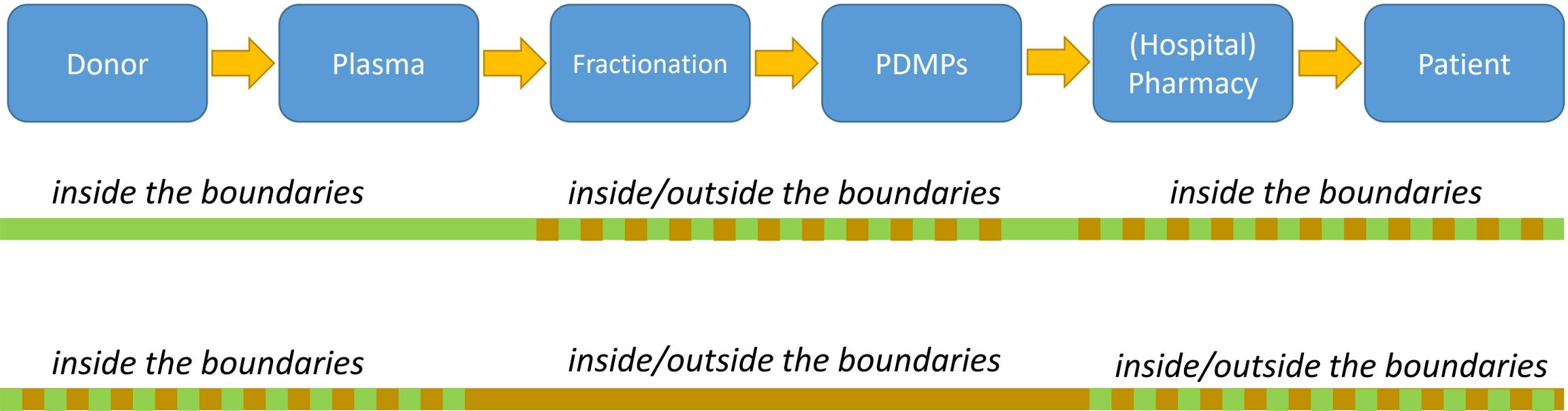
The plasma value chain



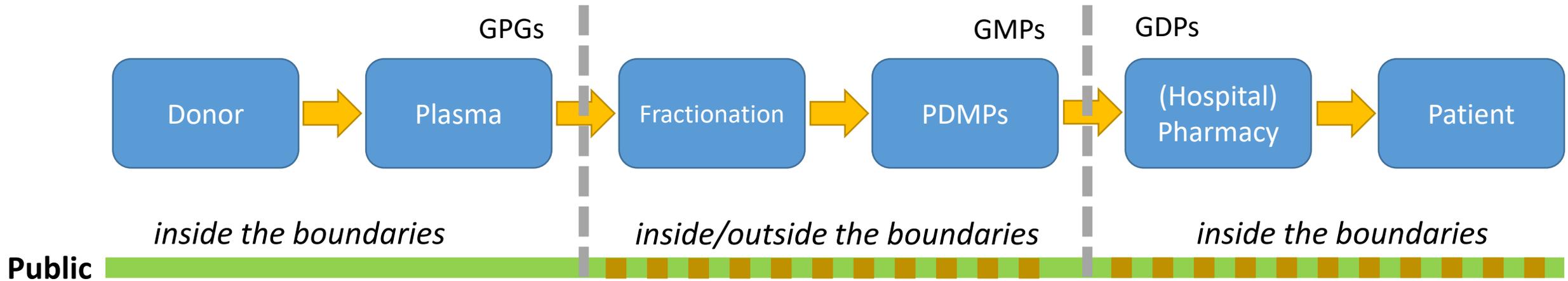
The plasma & PDMPs chain



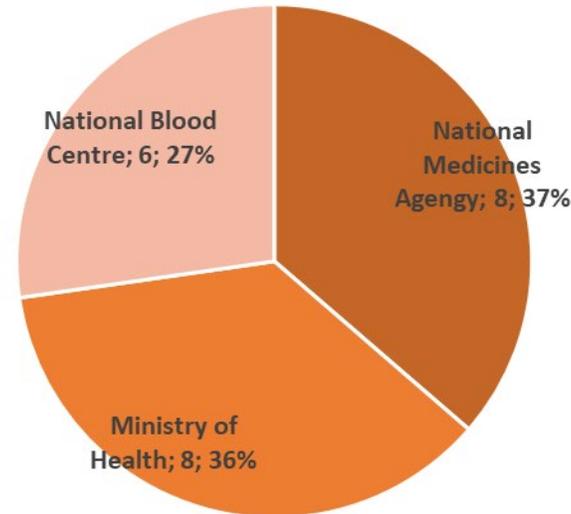
The plasma & PDMPs chain



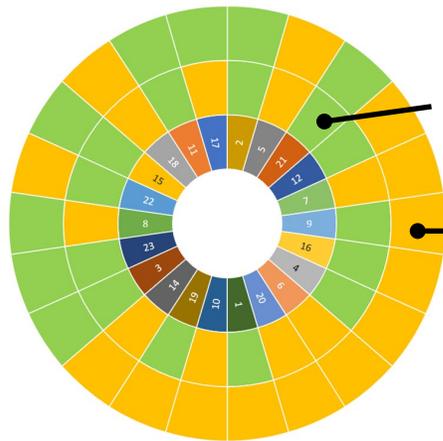
The plasma & PDMPs chain



Who is in charge of Plasma collection and PDMPs production from national plasma

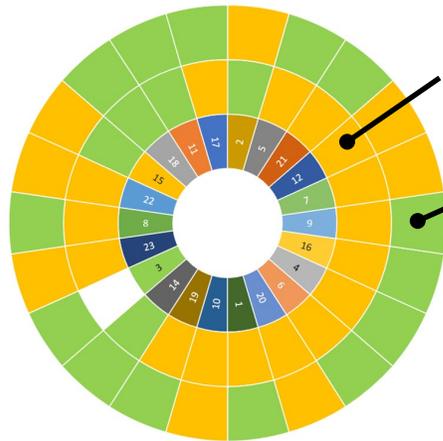


The plasma & PDMPs chain



Countries with a specific **legislative framework** on the collection of plasma intended for fractionation into PDMPs

Countries with a national **programme/policy** on the collection of plasma intended for fractionation into PDMPs

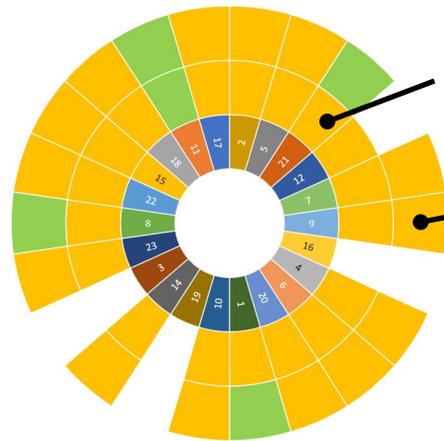


Countries with a specific **legislative framework** on the appropriate and rational clinical use of PDMPs

Countries with a specific **programme/policy** (e.g. guidance documents, recommendations) on the appropriate and rational clinical use of PDMPs

- Yes or Available
- No or Not available

The plasma & PDMPs chain



Countries with a specific **legislative framework** on prioritising use of PDMPs

Countries with any **guidelines/indications** on prioritising use of PDMPs



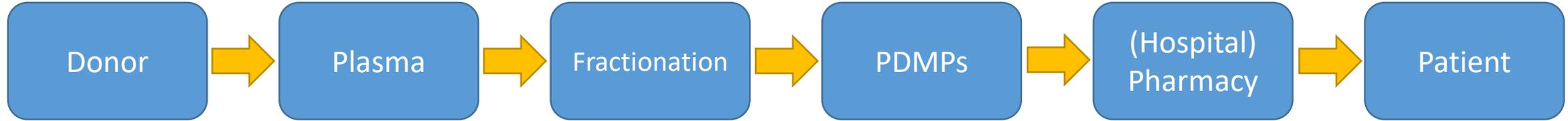
Country with a specific **legislative framework/policy** on exceeding PDMPs

Country with a specific **legislative framework/policy** on PDMPs shortage (e.g. mandatory storage and/or contingency rules)

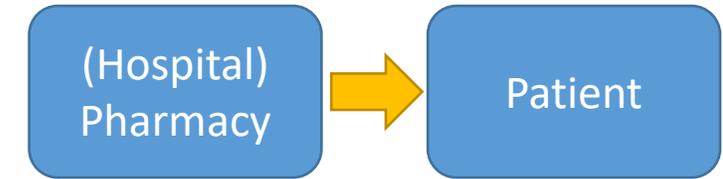
Yes or Available

No or Not available

The plasma & PDMPs chain



The plasma & PDMPs chain



Assessment of needs -

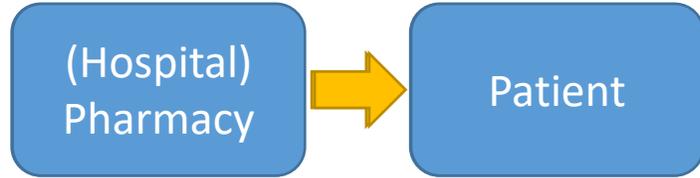
Analysis of the demand for driver(s) -

Analysis of the demand for other PDMPs -

Analysis of spatial and temporal trends -

Evaluation of clinical appropriateness -

The plasma & PDMPs chain



Assessment of needs -

Analysis of the demand for driver(s) -

Analysis of the demand for other PDMPs -

Analysis of spatial and temporal trends -

Evaluation of clinical appropriateness -

Analysis of

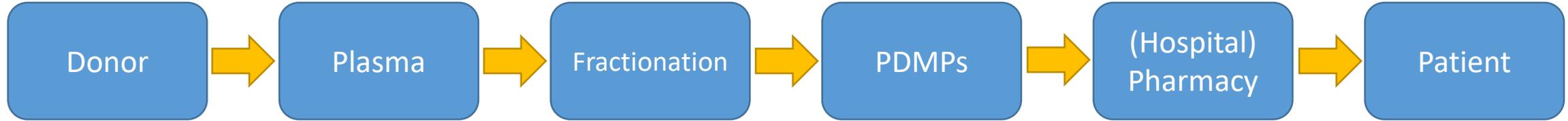
- Volumes of Plasma for fractionation available today and dynamics of the global context

- Planning of a sustainable plasmapheresis collection programme

- Impacts of the programme on the organisation of the BEs network and collection costs

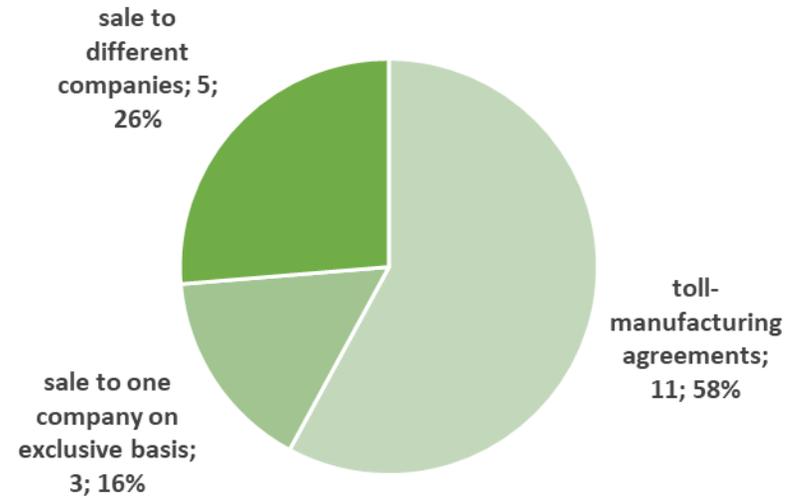
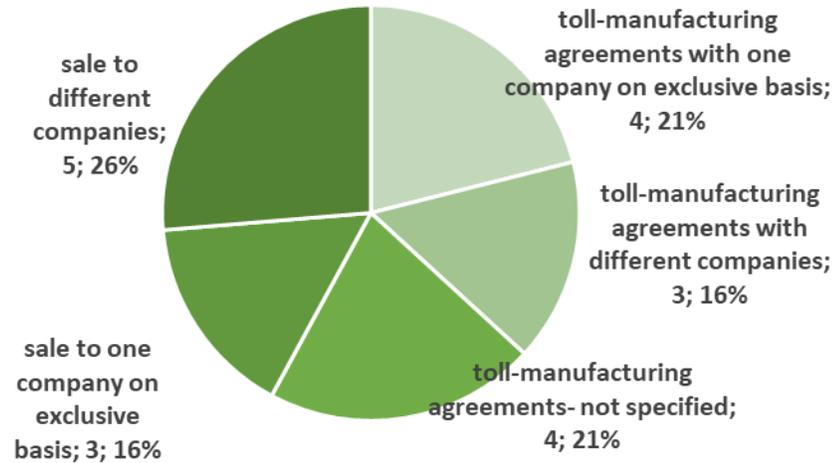
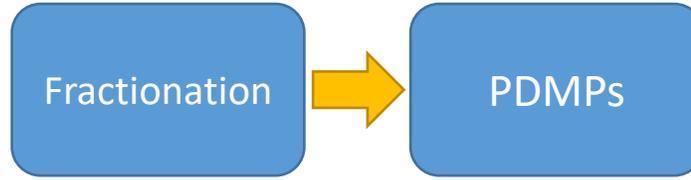
- Impacts of programming on pharmaceutical expenditure

The plasma & PDMPs chain



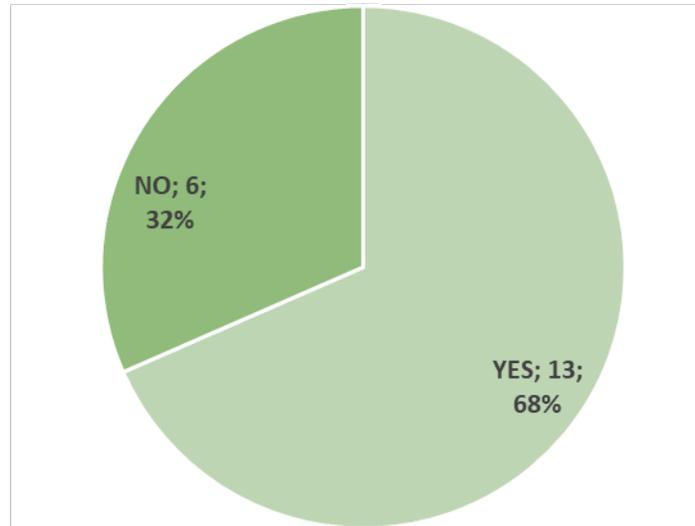
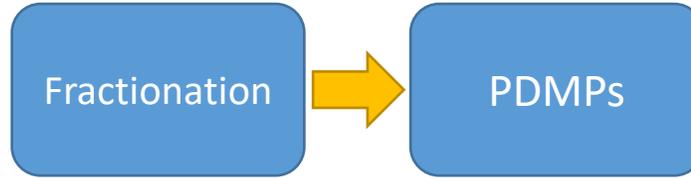
The plasma & PDMPs chain

EU MS manage the plasma collected under different manufacturing models, broadly belonging to two main systems :



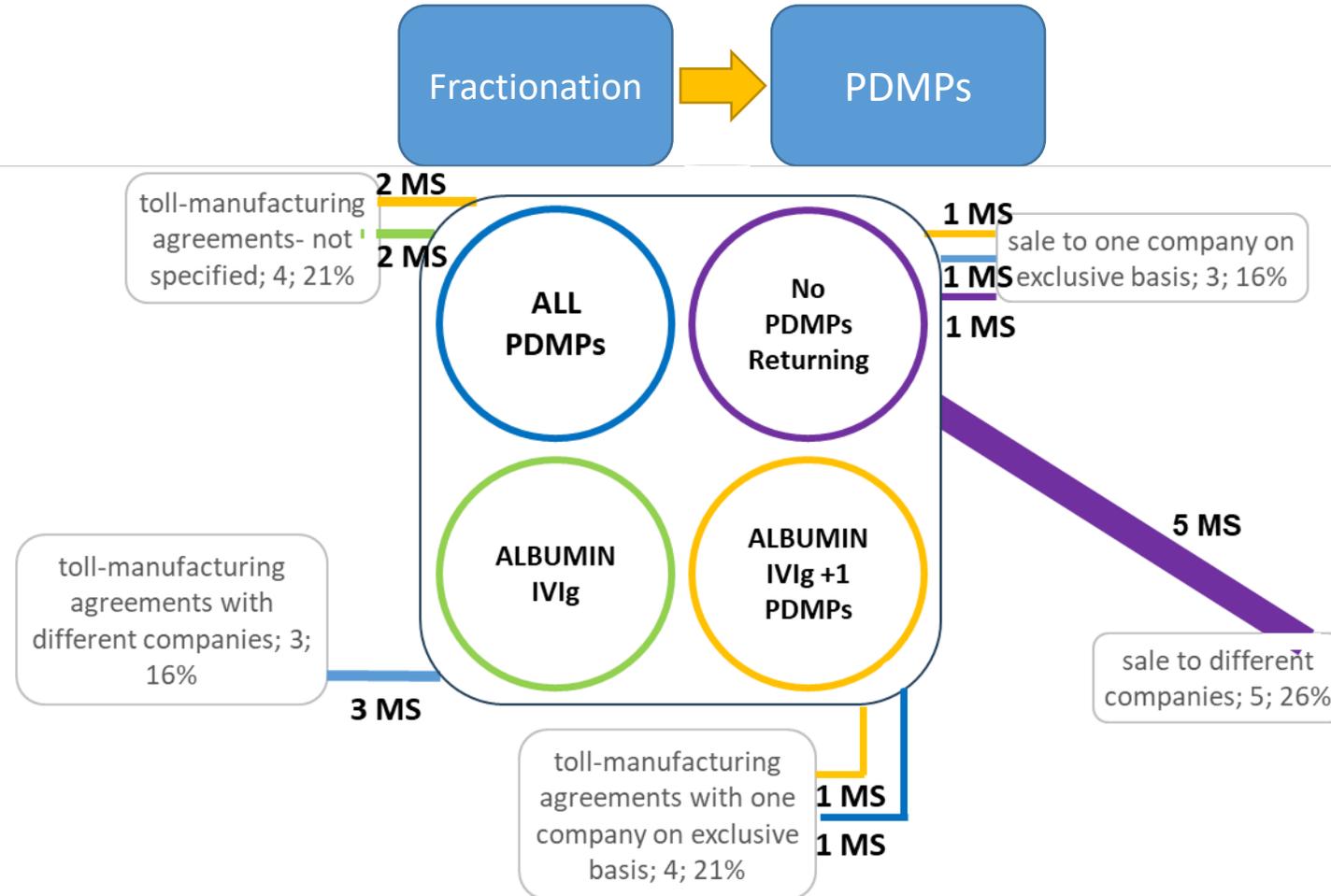
The plasma & PDMPs chain

EU MS
where PDMPs from
national plasma return
to the origin:



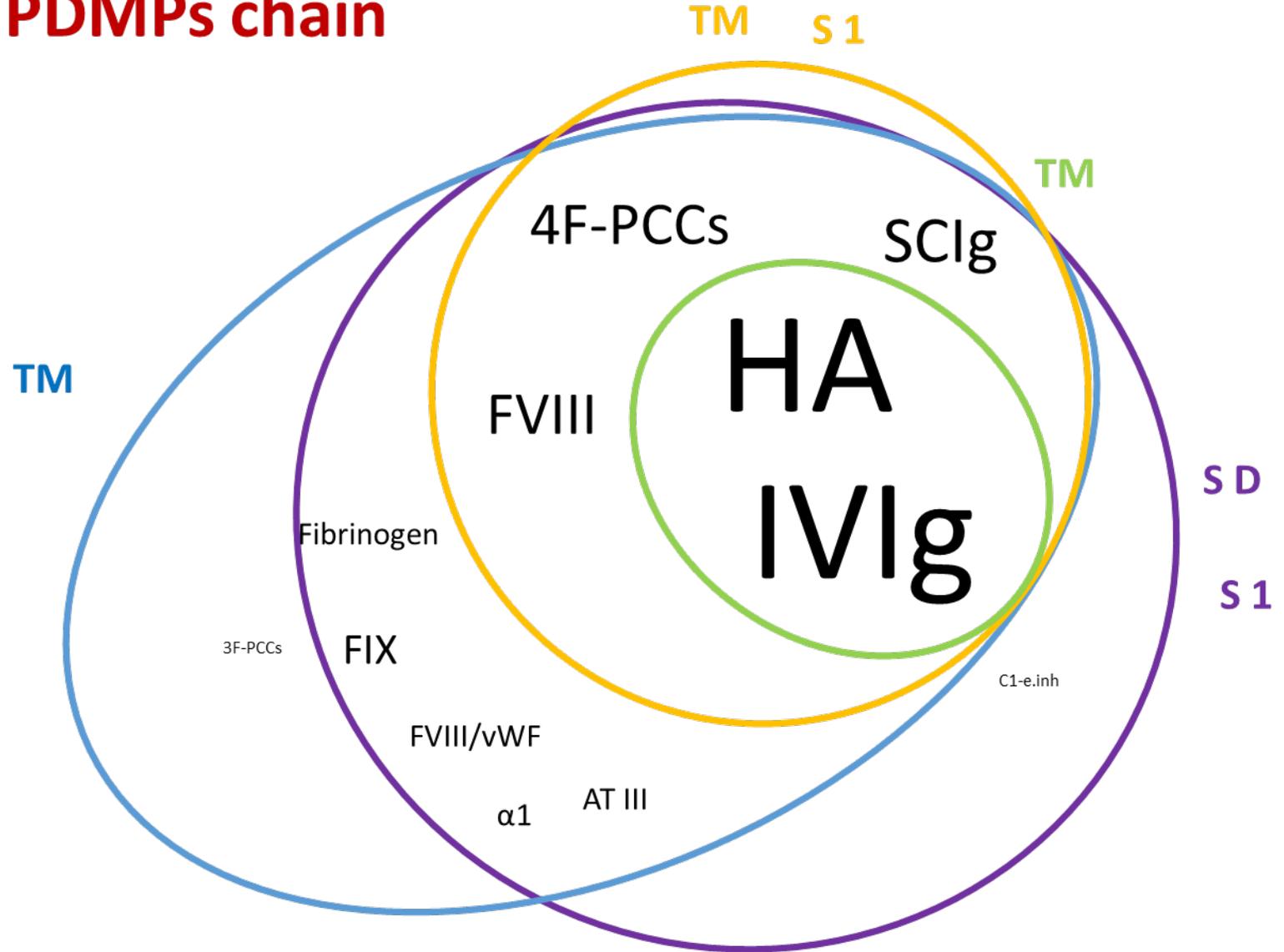
The plasma & PDMPs chain

Cross-Ref EU MS manufacturing models and PDMPs from national plasma return to the origin:



The plasma & PDMPs chain

EU MS
where PDMPs from
national plasma return
to the origin:

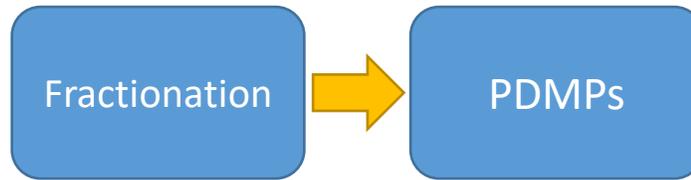


- All PDMPs return
- Drivers + 1 PDMP
- Only drivers
- No PDMPs return (free market purchasing)

Legend
TM: toll-manufacturing agreements
SD: sale to different companies
S1: sale to one company on exclusive basis

These data are collected and analysed as part of the project "101056988/SUPPLY" which has received funding from the European Union's EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains

The plasma & PDMPs chain



No matter what the manufacturing model is in place, national, regional, local tenders should consider:

Quantity and quality of Plasma for fractionation

Higher volumes of Plasma for fractionation find higher commercial interest from the (private) fractionators

Overall IgG concentration in plasma contributes to a more abundant supply of final products. An IgG based pricing model may put emphasis on this crucial parameter

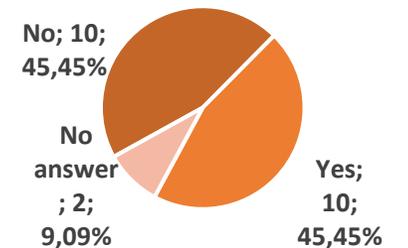
Commercial yields¹ for drivers manufacturing

Benchmark for assessing the return in products from the fractionation of domestic plasma (3.5 - 5 g/kg)

Market prices for drivers and other PDMPs

Benchmark for the extrinsic value of the plasma collected within Public facilities

Q34. Access to market prices



1. Plasma provided vs approved products made out of it

Source: - Adapted from von Bonsdorff L, et al. Securing commitment and control for the supply of plasma derivatives for public health systems. I: A short review of the global landscape. Vox Sang. 2025;120:114–23.

...securing the control for the supply of PDMPs

...securing the control for the supply of PDMPs

Information on the plasma & PDMPs chain should be available to NCAs;

Transparency and dissemination of information on all the plasma & PDMPs chain

vertical: from Local Health Authorities to NCAs to European/International bodies

horizontal: between NCAs at national level (Blood/SoHO CA ↔ Pharma CA),

at European and international levels (e.g. EDQM, EMA)

inwards the System: to all stakeholders (patient organisations, donor association, scientific societies, health authorities, regulatory authorities, pharma companies and fractionators, etc.);

Participatory approach involving all stakeholders in designing the National (and Local) Health Policies addressed to:

Planning of the collection, tendering processes, clinical use, etc.;

Awareness of the complexity of the PDMPs brings all the stakeholders to contribute to the optimal achievement of the objectives;

Provides elements for the improvement of competition.

...securing the control for the supply of PDMPs

European bodies should consider that the SUPPLY survey should be administered on a routine basis (yearly? biannual?) and become an instrument for transparency, monitoring, decision making, communication on plasma & PDMPs

...securing the control for the supply of PDMPs

Identification of a NCA or strengthen the collaboration among different NCAs that ensure:

- Planning of collection according to identified appropriate needs
- Monitoring of the process (from collection of PfF to distribution and clinical use of PDMPs)
- Monitoring the pharmaceutical expenditure on PDMPs (and their therapeutic alternatives)
- Long-term sustainability

At the very last point, “Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures*”.

Accessing raw material

- If the PDMPs manufacturing is essentially addressed to the drivers production (mainly IgG) what is the role of other fractions?

- In some manufacturing models they are left to the manufacturer and partially valued to define the selling price
 - In some manufacturing models they are used to produce other PDMPs offered by the fractionator

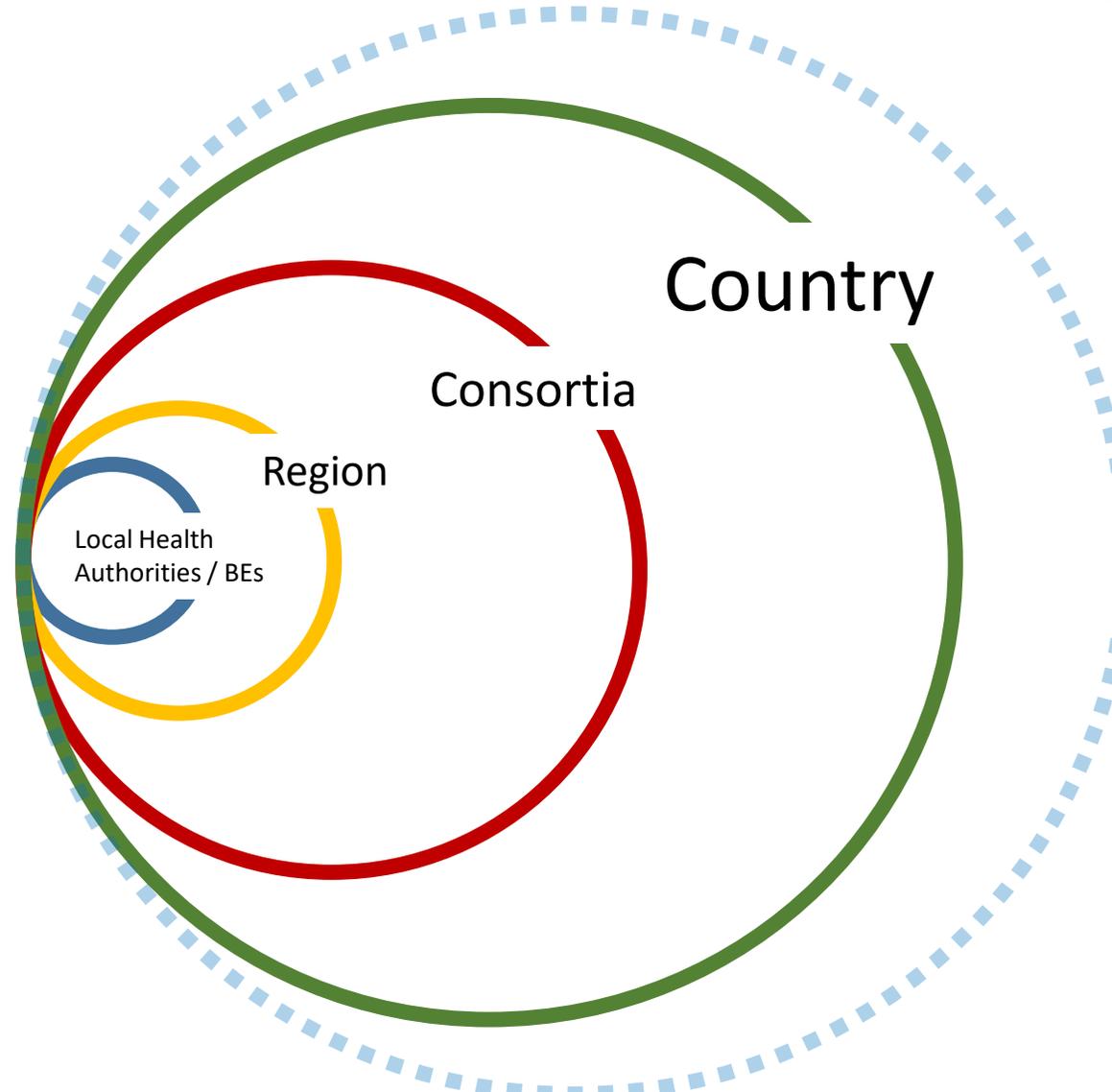
In any case they usually exceed national needs (e.g. FVIII, FIX) and could be made available and benefit European or low- and middle-income patient communities

Self-sufficiency

“[...] the capability to ensure to patients, in a systematic and sustainable manner, the ready and continuous availability of a defined set of PDMPs with the highest degree of quality and safety and in accordance with the existing regulatory framework, meeting appropriate clinical needs through national plasma collection based on voluntary, non-remunerated donations with the contribution of market-acquired shares.”

vs

Strategic independence



“[...] the capability of Health Systems to release and make autonomous the PDMPs supply from global market dynamics”.

Strategic distance
from childish behaviour in a context where...

Reinforcements

Within the framework of the Council of Europe, Member States are obliged to respect the principles enshrined in the Conventions to which they are party.

In particular, the **Oviedo Convention (Convention on Human Rights and Biomedicine)** establishes in **Article 3** that:

“Parties*, taking into account health needs and available resources, shall take appropriate measures with a view to providing equitable access to appropriate health care of good quality”.

This principle of equity constitutes both a legal obligation and a fundamental ethical reference point for national health policies.

* Member States of the Council of Europe

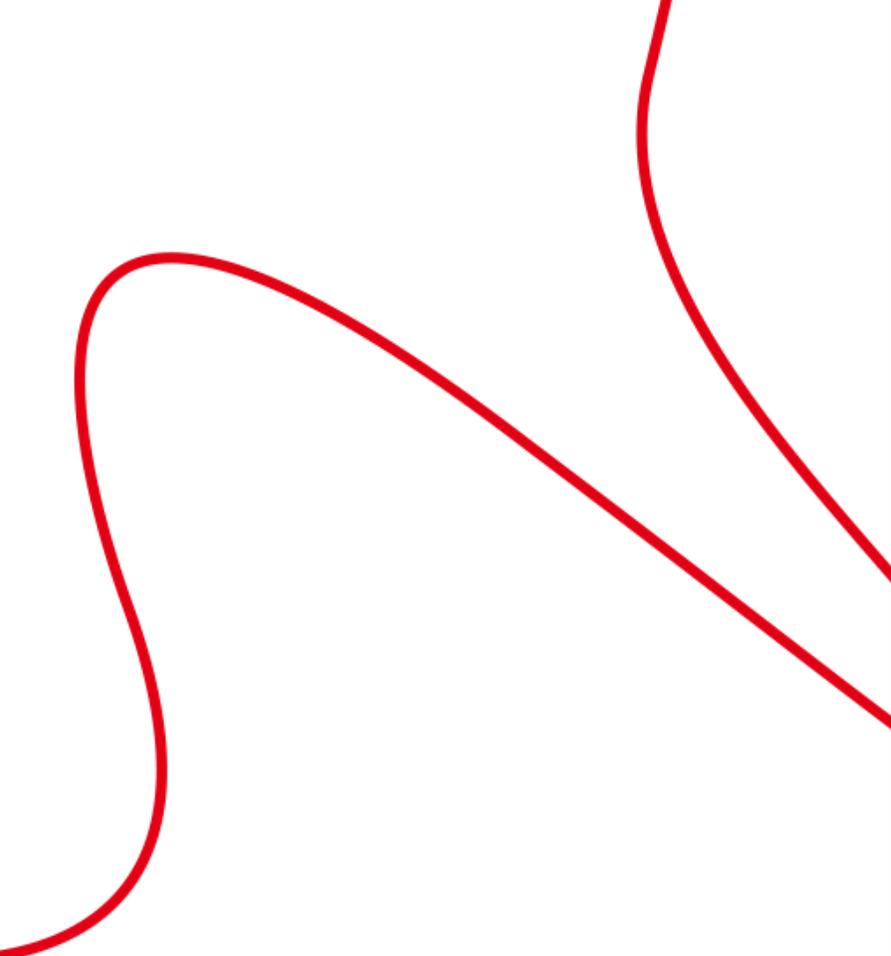


**Donnons
au sang
le pouvoir
de soigner**



PLASMA AMBITION 2025-2028

EFS strategic plan for plasma



Disclosures

- **EFS employee**
- **No disclosure**

GENERAL INFORMATION

- **EFS is the only BLOOD DONATION stakeholder in France**

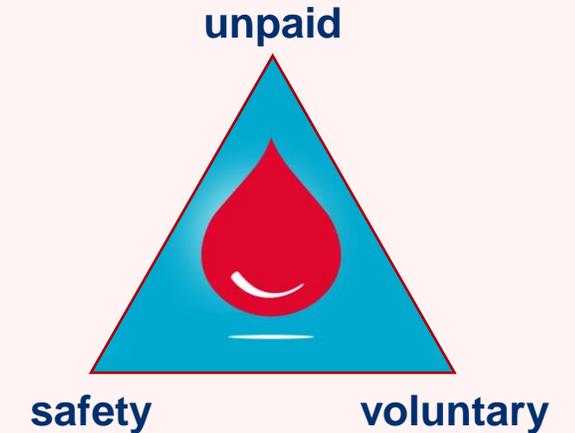


More than **1.5** million blood donors every year

- **We are linked with the French fractionator (LFB) :**

- EFS has volume target → plasma collected is only supplied to LFB
- Price are fixed
- LFB produces PDMPs from French plasma donors in priority for issuing in France

Our framework



PLASMA AMBITION – CONTEXT

A long term process

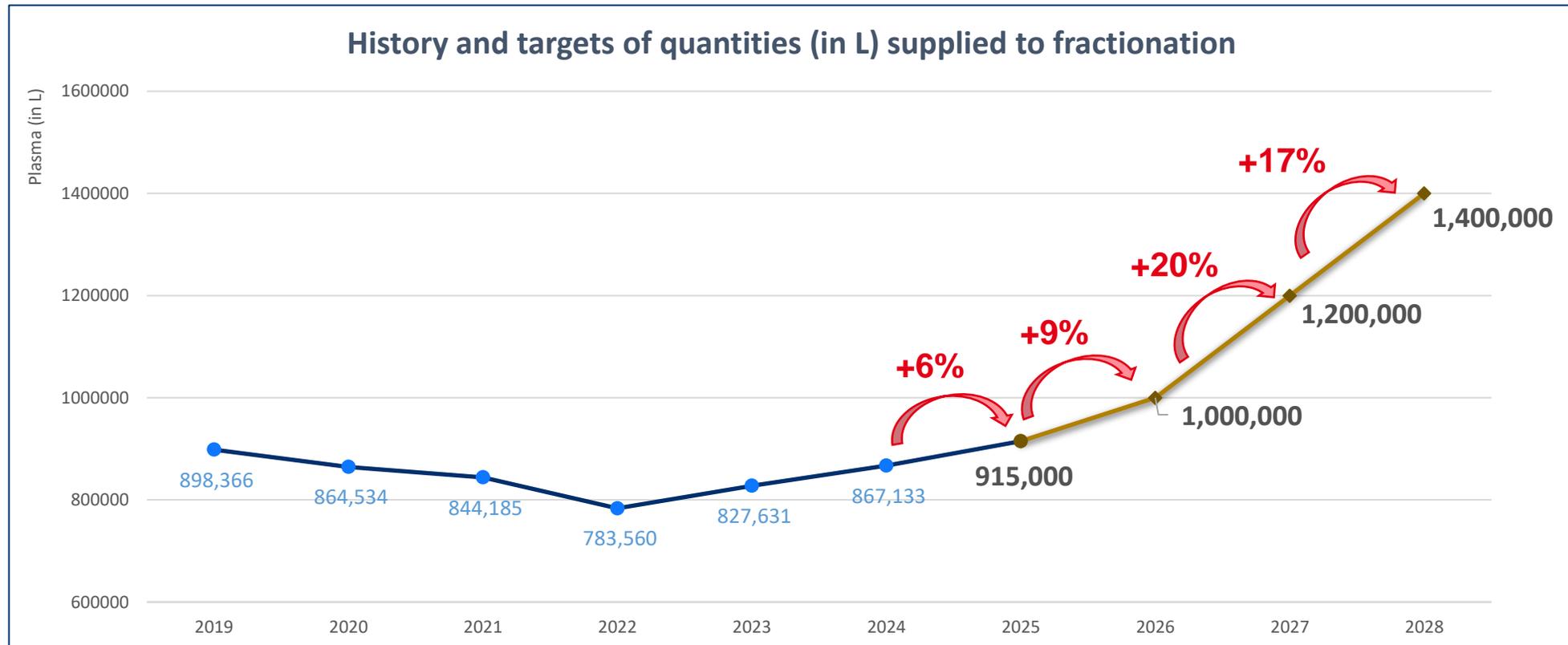
- Before COVID pandemic : we have discussed about the needs and how to achieve them.
- **2023 : a mission** from two French competent authorities (Health and Finances)
- **Today : 30 to 35% of IG needs** are covered with plasma collected **from French donors.**

Guidelines

July 2024, a letter with the guidelines sent by two ministers :

- **Increase the French** (and European) **health sovereignty** : reduce dependency on importations and provide patients with sustainable access to PDMPs.
- **Deadlines and targets**
- Financial support
- Monitored by a committee

PLASMA AMBITION – THE TARGETS



- Past years : a sharp decrease of recovered plasma.
- **2025 represents a historical peak.**

STRATEGIC PLAN



2025: 915 KL

2026: 1,000 KL

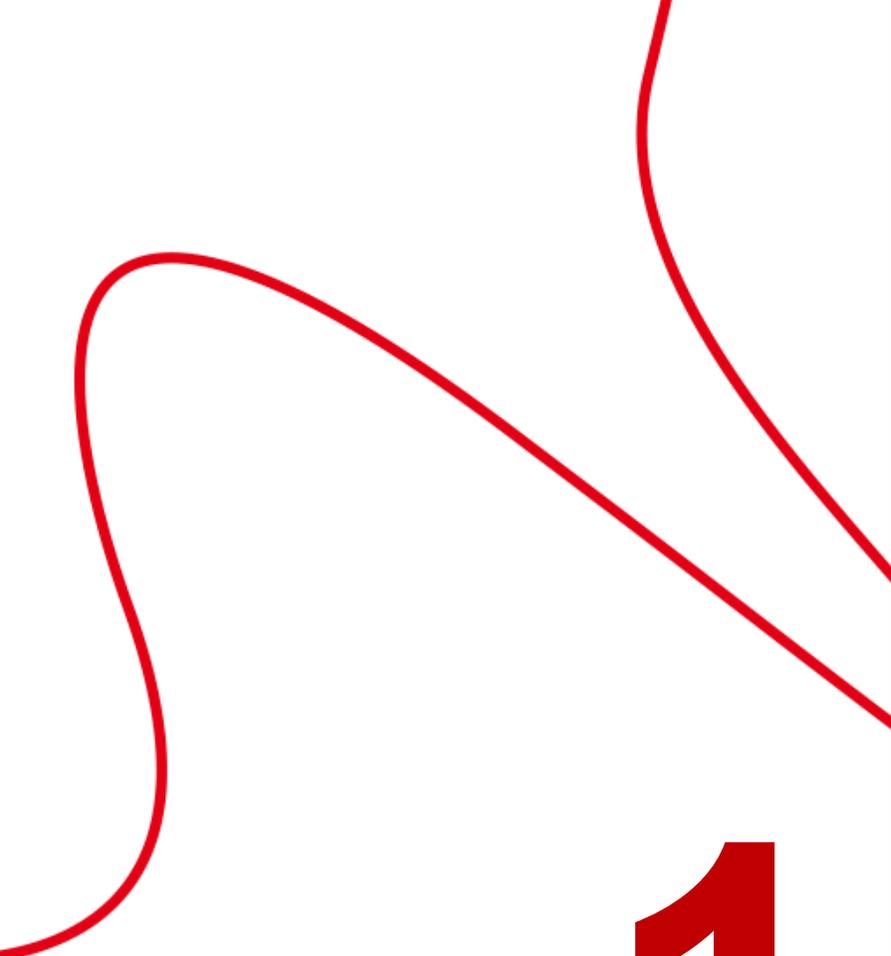
2027: 1,200 KL

2028: 1,400 KL

Invest in human and financial capital to enhance plasma collection capacity

4 DIRECTIONS

1. Donation centers
2. Devices
3. Human resources
4. Donor recruitment and retention processes



1

THE COLLECTION OFFER

EFS Plasma donation mapping (2024)

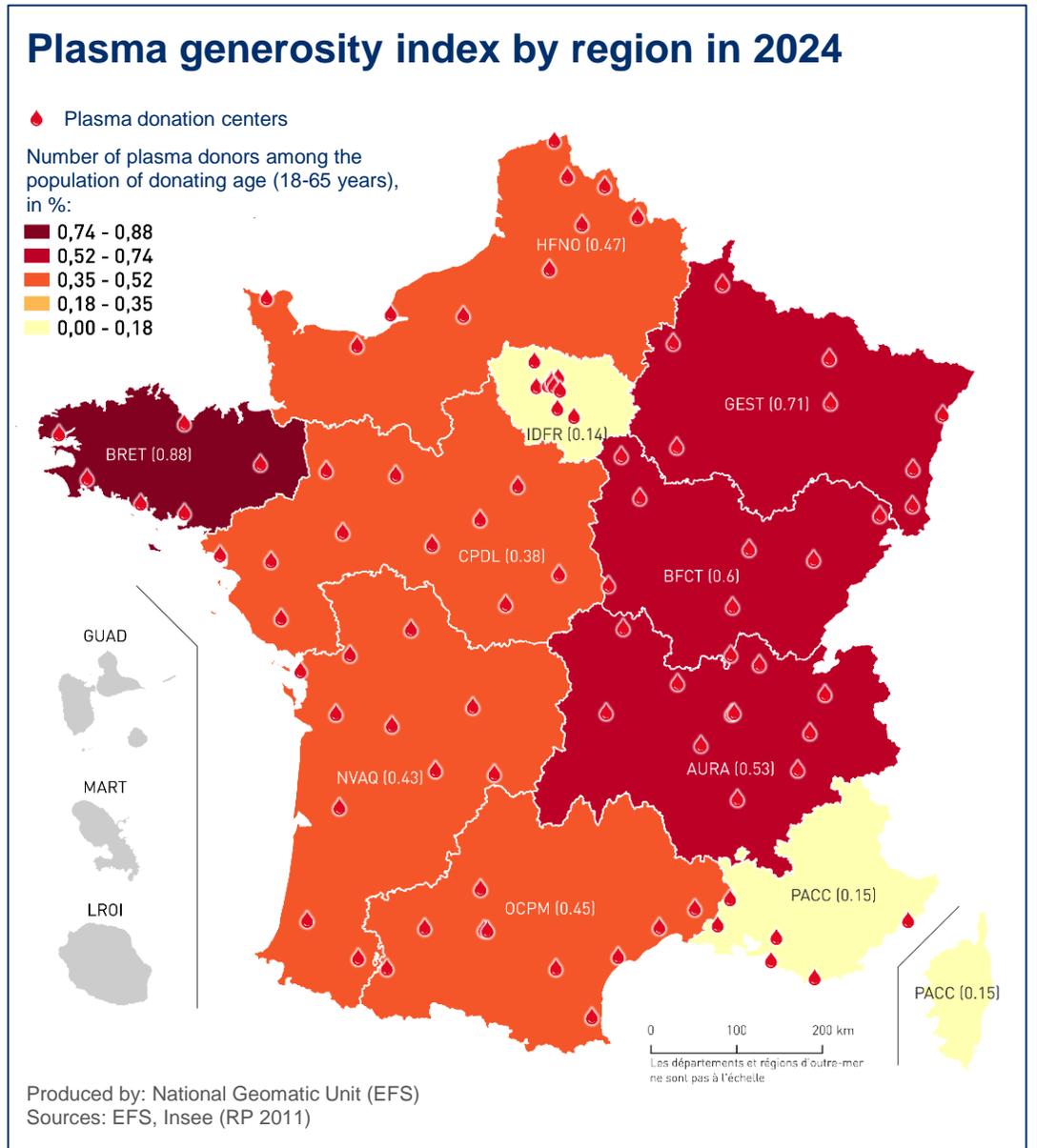
↪ **93 (hybride) centers with 496 devices**

↪ **160K donors (+14% vs. 2023) :**

= 0.40% of eligible population (18-65 y)

↪ **382,956 plasma donations (+16% vs. 2023)**

↪ **2.4 average donations / year**



OUR FACILITIES

1. OPTIMIZE EXISTING CENTERS

- **Fully exploit** plasma collection **capacities** in existing donor centers :
 - **Extension of opening hours** (in the evening and at weekends)
 - **Addition of collection beds**
- **Resume plasma collection**

2. DEPLOY A REAL ESTATE TRAJECTORY

- **Renovate / modernize** donor centers → schedule 2 to 4 /years
- **Extend** existing donor centers
- **Move** donor centers
- Create **new donor centers** → 20 projects (*identified via geomatic*)
- **Experiment** new donation sites (*e.g. pop-up centers*)





2

THE DEVICES

Acquisitions of new devices to support the scale-up

Recovered volume stabilization → **Source plasma is the key driver of growth!**

1

Almost double the number of plasmapheresis devices :

→ 39 acquired in 2024

→ 25 budgeted for 2025

2

New device/disposal in order to secure supply and reduce costs

Ongoing tests and validations



Implementation planned for 2026

→ *In parallel : authorities expertise on the leukoreduction specifications, in order to align (or not) with European standard*

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3

HUMAN RESOURCES

STRENGTHENING HUMAN RESOURCES



≈ 400 recruitments planned

BOOST EFS EMPLOYER BRANDING AND EMPLOYEE RETENTION

- **Enhance individual skills and foster versatility** (work in blood centres and mobile drives, access to new jobs : remote medical assistant, blood collection supervisor,...)
- **Review our classification of occupations** (salary competitiveness)
- **Train teams to raise plasma awareness**
- **Develop an effective change management strategy** → managerial issue

DEFINE NEW ORGANISATION MODELS

- Reflect on **more flexible work organization** and **more optimized** at blood collection
→ **Balance between productivity / quality of work life (QWL) / meet donor expectations**
- **Optimize donor care and the donation process: *digital health quiz...***



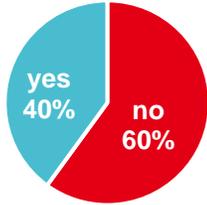
4

DONOR RECRUITMENT AND LOYALTY

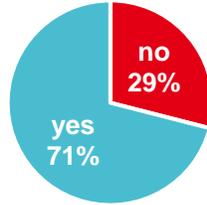
COMMUNICATION AND MARKETING STRATEGY

Survey in France in 2024

Do you know
plasma donation?



Do you know
blood donation?



Develop **plasma donation awareness** to the public

→ National to local public **multichannel campaigns**

EFS budget amount of 1.3 M€ in 2025

→ Institutional and media support

→ **Strengthening the EFS brand:** public service for patients, sovereignty...

Plasma generosity index

→ **1% in 2028**

Recruiting 60 to 100,000 new donors/year

→ Conversion from **WB donation to plasma** donation

→ Targeted and **personalized marketing actions**

→ **Involvement and support of all EFS partners**

→ Development of our digital services (website, app)

Loyalty index

→ **3.2 per donor in 2028**

Work on **plasma donor loyalty** according to their characteristics

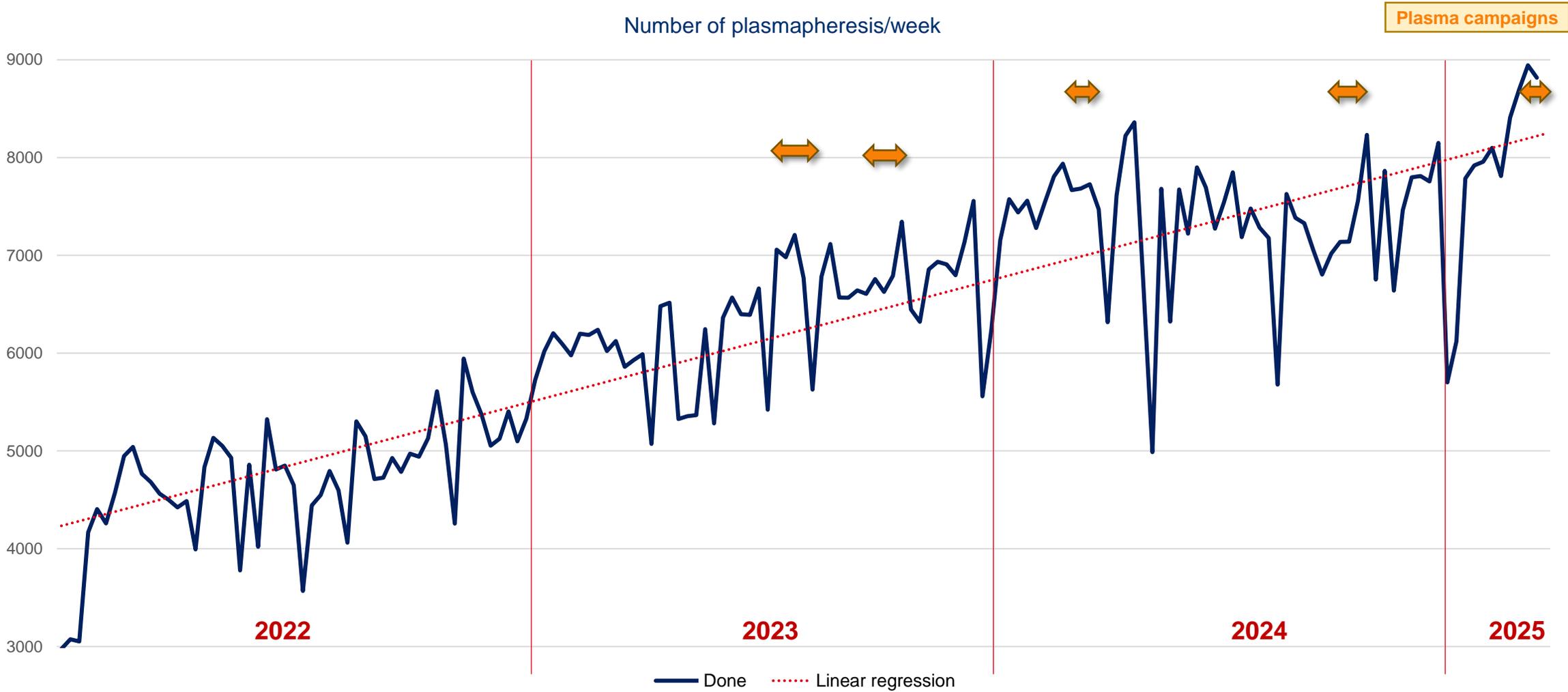
→ **Personalized marketing contact plans**

→ **Plasma donor recognition programs:** digital badges for donation milestones, patients testimonials...

→ **Comfortable and user-friendly donor centers**

FIRST RESULTS: A DYNAMIC IN PLACE

2024 represented the record number of plasmapheresis in 12 years!



DISCUSSION

- **A short timeline.**
- **A dual challenge** : find and maintain **whole blood** donor and increase **plasma** donors
 - complete the EFS donor plasma campaign with government support
- Finding **the right balance between volume and efficiency** (to meet productivity requirements) :
 - How to address donors in Paris area or those far from our centers?
 - Staff recruitment and retention issue
- **Vendor/manufacturing risk.**

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5

CONCLUSION

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- The **plasma ambition program** represents a significant quantitative leap and also represents a strong signal for:
 - Increase **French self-sufficiency** in PDMPs (**sovereignty**),
 - and an **opportunity** to renew and consolidate our **ethical plasma collection model**.

- A challenge will be to **preserve the overall economic balance** of the EFS.

- **EFS can count on a number of assets to achieve this goal**, among which:
 - the **skills and expertise** of its teams,
 - its demonstrated **adaptability**, always with the respect of **security**,
 - its **connection with donors, donation partners, and citizens !**



THANK YOU!

CONTACT

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