The supply of plasma-derived medicinal products in the future of Europe

*Second edition*

23-24 April 2024
Rome, Italy

CENTRO NAZIONALE SANGUE

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# SUPPLY Project in a Nutshell

**Peter O'Leary**
*SUPPLY Project Co-ordinator*
*and Executive Director, European Blood Alliance*

# Disclosure

I have no conflicts of Interest to Declare

# Background to the SUPPLY Project

- Patients need continued and stable access to Plasma Medicines (vs Shortages)
- Growing clinical needs for Plasma Medicines
- Increasing global dependence on plasma collected in the USA, including in Europe
- Urgency to build resilience for crisis situations (COVID etc)
- Availability of Plasma medicines is driven by a world-wide competitive market
- Sufficient collection of plasma by a country ≠ sufficient supply of Plasma medicines for its patients
- Large differences in the usage of IgG (particularly) between countries

- September 1 2022, the SUPPLY project started.

  Co-funded by EU4Health programme

- Feb 29 2024, SUPPLY project completion


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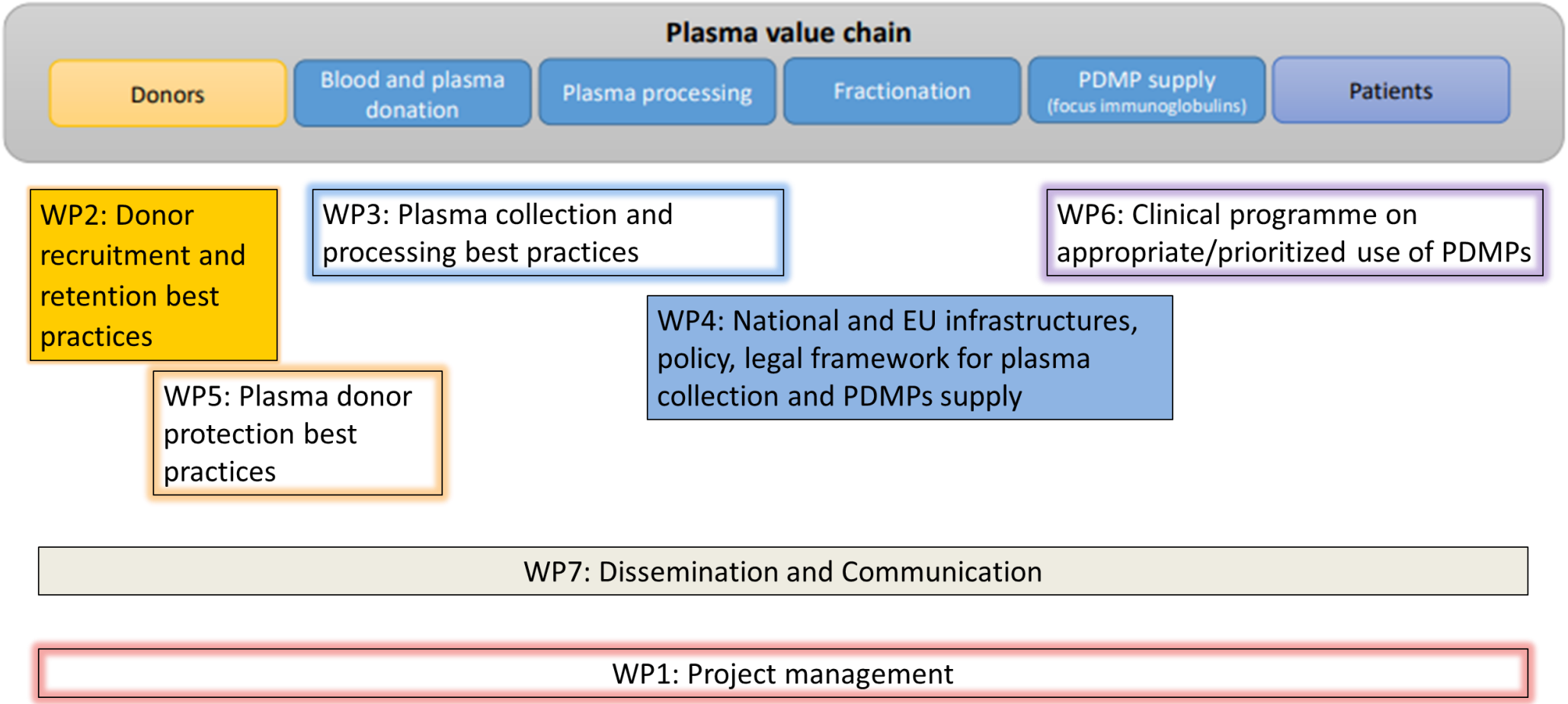


Aim: To develop good practices, guidance, and recommendations to

- Increase the volume and resilience of unpaid plasma collection in Europe by the public health sector

and

- Ensure safe, sufficient, and stable access for EU patients to essential Plasma Medicines

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# SUPPLY Consortium

| Participant organisation name | Short name | Country | Role |
|---|---|---|---|
| European Blood Alliance | EBA | The Netherlands | COO |
| Etablissement Français du Sang | EFS | France | BEN |
| Stichting Sanquin Bloedvoorziening | SQ | The Netherlands | BEN |
| Belgische Rode Kruis | RKV | Belgium | BEN |
| Universitaet Hamburg | UH | Germany | BEN |
| DRK-Blutspendedienst Baden-Wurttemberg-Hessen GGMBH | DRK-BSD | Germany | BEN |
| European Hematology Association | EHA | The Netherlands | BEN |
| International Plasma and Fractionation Association | IPFA | The Netherlands | BEN |
| Bloddonorerne I Danmark | DBDO | Denmark | AP |
| Istituto superiore di sanita | CNS | Italy | BEN |
| The Scottish National Blood Transfusion Service | SBTS | UK | AP |
| International Federation of Blood Donor Organisations | FIODS | Italy/ Monaco | AP |
| Servicio Vasco de Salud Osakidetza | CVT | Spain | BEN |
| Irish Blood Transfusion Service | IBTS | Ireland | BEN |
| Aarhus Universitet Hospital | AUH | Denmark | BEN |
| Osterreichisches Rotes Kreuz | RKA | Austria | BEN |
| Zavod Republike Slovenije Za Transfuzijsko Medicino | BTCS | Slovenia | AP |
| Ministerio De Sanidad | SCTS | Spain | AP |
| PHI Institute for Transfusion Medicine of RNM | ITM | North Macedonia | AP |
| Instituto Portugues do Sangue e da Transplantacao IP | IPST | Portugal | BEN |

**As the project outputs are those of the SUPPLY consortium, they cannot be considered to necessarily reflect the views of any individual organisation which forms part of the consortium.**



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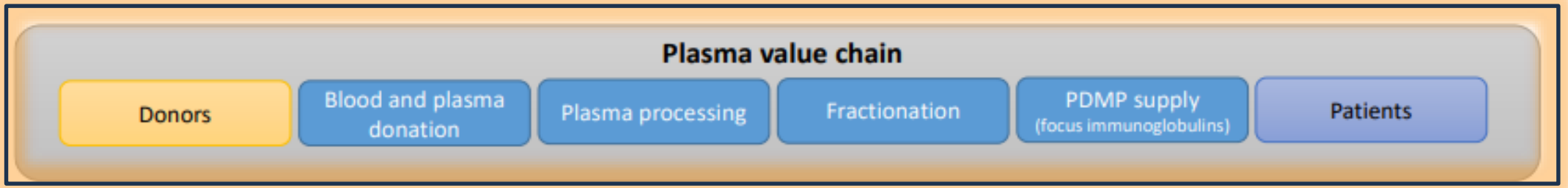
# SUPPLY

## Work Package 1
## **Project Management**

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# Crisis Situations – The impact on the plasma-PDMP-patient chain: Analysis and Recommendations (Scenario Evaluation Plan)

- Analyses the potential impact of crisis situations (pandemic, war, climate change, and trade-war) on the Plasma-PDMP-Patient chain, links to SUPPLY reports, and provides Recommendations

- Informs, complements, and assists with:
  - EU and national plasma strategies
  - National SoHO emergency plans and Critical SoHO Entity emergency plans (SoHO Regulation)

**Overview findings**:

1. Plasma is a critical medical raw material and a public resource that requires strategic management.

2. Policymakers, healthcare providers, and stakeholders must work collaboratively to proactively address the risks identified

3. Requisite measures should be implemented during periods of relative calm to ensure the plasma and PDMP system is robust and resilient in times of crises.

4. During crises, public non-remunerated plasma (and other SoHO) collection programmes have proven more resilient than private plasma collection programmes.

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# Crisis Situations – The impact on the plasma-PDMP-patient chain: Analysis and Recommendations (Scenario Evaluation Plan)

*Selected Recommendations - General:*

- Countries should increase their collection capacity and donor base for plasma by developing non-profit and public plasmapheresis programmes.
- National governments should liaise with Blood Establishments and Invest in Plasma system improvements
- Create legal conditions to eliminate any barrier against the pooling of plasma from different EU Member States and promote agreements among 2 or more Member States
- EU and Member States should run campaigns to promote information and awareness on the importance of plasma donation
- Ensure efforts to increase plasma collection do not erode the current non-remunerated SoHO donor population

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# Crisis Situations – The impact on the plasma-PDMP-patient chain: Analysis and Recommendations (Scenario Evaluation Plan)

*Selected Recommendations - PDMPs:*

- EU and National Governments must monitor PDMP trends and availability, particularly Ig, and appropriate clinical utilisation
- Ensure sufficient control and monitoring over the plasma-PDMP-patient chain, ideally through legislative guarantees
- Prioritise and resource Toll Fractionation / Contracted Service tender models
- Include protein yields, Ig content, and recovery percentages in tenders
- Create a harmonised national Ig database to best measure Ig usage at baseline and in times of crisis
- Investing in research and development to reduce dependence on PDMPs and/or to develop alternative therapies may provide long-term solutions. [possibly through IPCEI* instrument]

*IPCEI – Important Projects of Common European Interest

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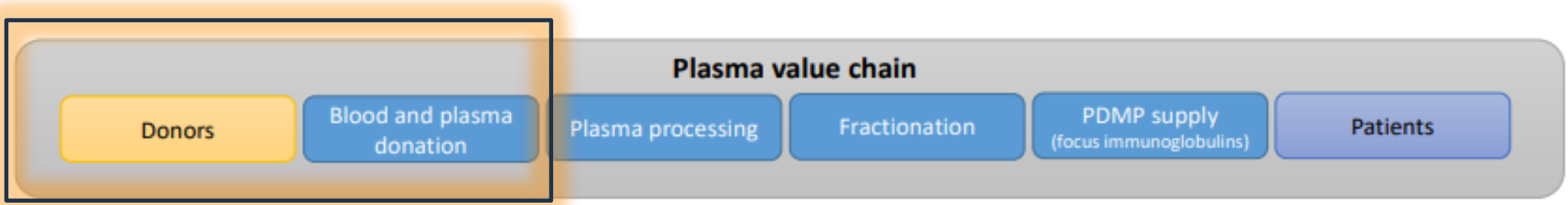
# Work Package 2

# Donor Recruitment and Retention Best Practices

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# Objectives & Recommendations

## Objectives

**Deliverable 2.1**

Overview of plasma donor recruitment and retention strategies

**Deliverable 2.2**

Assessing identified practices regarding efficiency and identifying novel practices

**Transfer plan**

Developing a recommendation and transfer plan

## Recommendations

- Snacks are provided in all countries and should remain in BE's incentive portfolio.
- Health checks are ranked well among all donor groups and across all countries.
- In non-remunerated countries, plasma donors are used to, and have a highest preference for, receiving no incentives. Recognition and health checks are also preferred.
- In remunerated countries, plasma donors are used to receive money and they prefer incentives with monetary value e.g. paid day-off

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# Results – Deliverable 2.1

| Country | Plasma collection | Data available | MARKET ATTRIBUTES | | | | INCENTIVES[1] | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Centralized plasma collection model | Organization type | | | Rung 6 | | Rung 5 | Rung 5 | Rung 4 Rung 5 | Rung 4 Rung 5 | Rung 2 Rung 4 | Rung 4 | Rung 3 | Rung 3 Rung 5 | Rung 2 | Rung 2 |
| | | | | Profit | State | Non-profit | Cash payment | Amount [€][2] | Referral program | Coupons | Lottery | Gifts | Health check | Loyalty program | Travel compen-sation | Time off work | Snacks | Enter-tainment |
| **EU countries** | | | | | | | | | | | | | | | | | | |
| Austria | Yes | ✓ | No | x | | x | x | 30-35 | | | | | x[c] | x | | | x | x |
| Belgium | Yes | ✓ | Yes | | | x | - | | x | x | | x | x[b] | x | x | | x | |
| Bulgaria[3] | No | - | - | | | | | | | | | | | | | | | |
| Croatia[4] | No | ✓ | - | | | | | | | | | x | | | | | x | |
| Cyprus[4] | No | ✓ | Yes | | x | | - | | | | | | x[c] | | | | x | |
| Czechia | Yes | ✓ | No | x | | x | x | 30 | x | x | x | x | x[b] | x | | | x | x |
| Denmark | Yes | ✓ | Yes | | x | x | - | | x | | x | x | | x | | | x | |
| Estonia | Yes | ✓ | Yes | | x | | - | | | | x | x | x[c] | x | | | x | |
| Finland[4] | No | ✓ | Yes | | | x | - | | | | | x | | | | | x | |
| France | Yes | ✓ | Yes | | x | | - | | | | | x | x[b] | | x | | x | x |
| Germany | Yes | ✓ | No | x | x | x | x | 20-30 | x | x | x | x | x[c] | x | x | | x | |
| Greece[3] | No | - | - | | | | | | | | | | | | | | | |
| Hungary[6] | Yes | ✓ | No | x | | | x | 13-26 | x | x | x | | x | x | | | x | x |
| Ireland[4] | No | ✓ | Yes | | x | | - | | | | | | | | | | | |
| Italy | Yes | ✓ | Yes | | x | | - | | | | | x | x[c] | x | | x[d] | x | |
| Latvia | Yes | ✓ | Yes | | x | | x | 17 | | | | | x[b] | | | x[e] | x | x |
| Lithuania[6] | Yes | ✓ | Yes | | x | | x | 12 | | | | | x | x | | | | |
| Luxembourg[6] | Yes | ✓ | Yes | | | x | - | | | | | | x | | | | x | |
| Malta[4] | No | ✓ | Yes | | x | | | | | | | x | | | | | x | |
| The Netherlands | Yes | ✓ | Yes | | | x | - | | x[a] | | | x | x[b] | x | x | | x | |
| Poland | Yes | ✓ | Yes | | x | | | | | | | | x | x | x | x[e] | x | |
| Portugal | Yes | ✓ | No | | x | x | | | | | | | | | | | x | |
| Romania[4] | No | - | - | | | | | | | | | | | | | | | |
| Slovakia | Yes | ✓ | No | x | x | | - | | x | | | x | | | | | x | |
| Slovenia | Yes | ✓ | Yes | | x | | - | | | | | x | | | | | x | |
| Spain | Yes | ✓ | No | | x | | - | | | | x | x | x[c] | x | | | x | |
| Sweden | Yes | ✓ | No | | | x | x | 10-15 | | | x | x | | | x | | x | |

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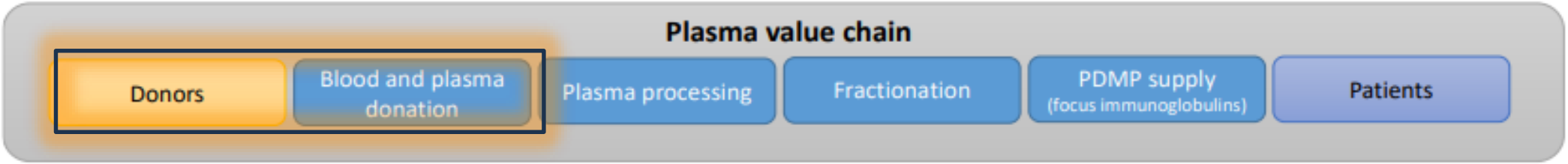
# Work Package 5
# Plasma Donor Protection best practices

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# WP 5 Plasma Donor Protection best practices

| T5.1, D5.1<br>Collect information on current plasma donor protection practices (survey and analysis report) | T5.2<br>Evaluate the available scientific evidence on plasma donor protection practices (scoping review and systematic review) | T5.3, D5.2<br>Describe requirements for a support tool on standardized donor vigilance data to be collected (report) |
|---|---|---|

T5.4, D5.3
Formulate (evidence-based) recommendations (report)

## D5.2: Protecting Plasma donor health: a Support Tool for standardised Plasma Donor Vigilance data

Collected information on current plasma donor protection practices and performed a gap analysis.

- Standardised classification of adverse events.
- This haemovigilance system can build the basis for an EU-wide IT-integrated solution and database.

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## D5.3: Recommendations on protection of plasma donors (part 1)

We recommend adherence to the Blood Guide (21st edition 2023) until further evidence is acquired and:

- A maximum of two plasma donations per month, pending sufficient evidence confirming the safety of higher donation frequencies. This recommendation is based on expert opinion and reflects the view of a majority of WP5 members.*
- Monitoring IgG levels. Evidence of optimal IgG algorithms and test intervals are lacking.
- Urgent initiation of prospective studies to examine the health consequences of plasma donation at varying frequencies.
- Implementation of a register for standardised haemovigilance data on a mandatory basis (D5.2)

* Alternative recommendation, supported by two WP5 members: a maximum of two plasma donations per month, unless a donor health and IgG management system is established by the respective blood establishment.

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## D5.3: Recommendations on protection of plasma donors (part 2)

WP5 Plasma Donor Protection recommendations stem from the precautionary principle, prioritising donor safety until more information is available.

- Further controlled experimental studies are needed to formulate recommendations regarding selection criteria, preventive measures, volume of plasma collected per donation, and safe donation frequencies.

- Register-based studies are needed for evaluating long-term health effects of (high-frequency) plasma donations.
  - Dropout rates and reasons will be monitored.
  - Relevant outcomes include ICD-10 codes from contacts with the healthcare system, relevant prescriptions of medicine, etc.

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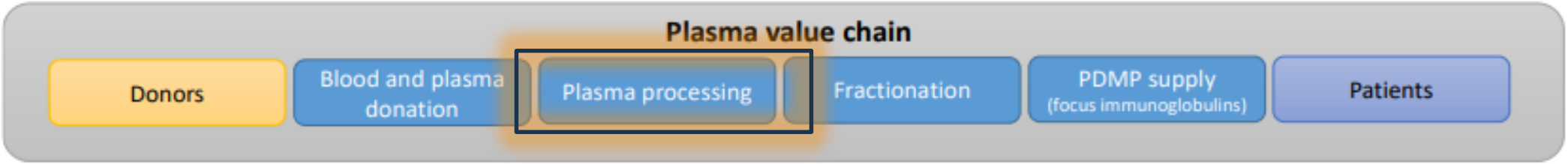
# Work Package 3
# Plasma Collection and Processing Best Practices

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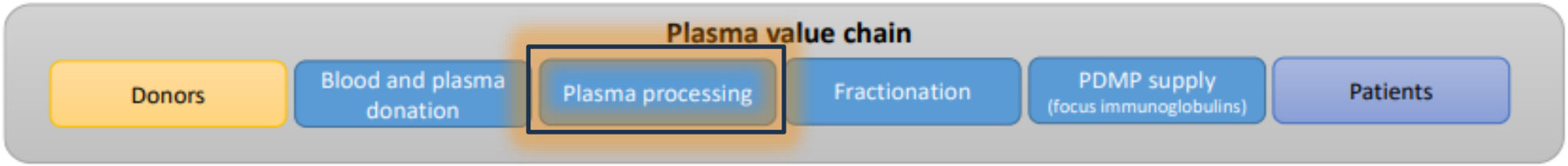


## WP3: Plasma Collection and Processing Best Practices

**Most important recommendations:**

- To meet the demand for plasma a formula (RADIUS) can be used to determine the optimal number of donor centres and their strategic location.
- Regulatory requirements should be simplified and modified to increase plasmapheresis programs and avoid waste.
- Focus on retaining donors and increasing donation frequency while also recruiting more donors.
- Invest in cost reduction programs to make the processes more efficient, for example by automation or digitalisation.
- Use the IgG concentration to determine the value of plasma as “low-frequency” donors have a higher concentration of IgG.

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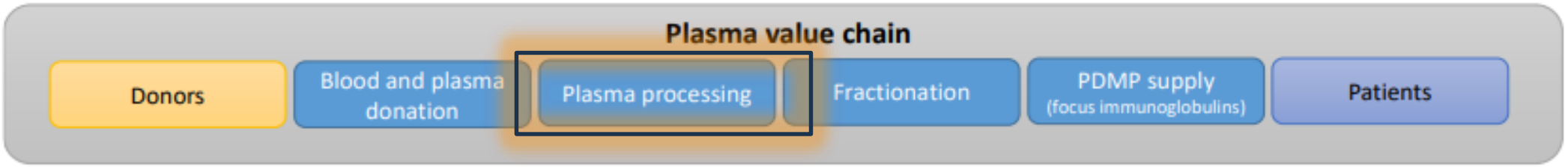


**D3.1: Setting up a Plasma Centre: Practical tools**

..for a systematic approach to:

demographic analysis, accessibility, geographical coverage, operational efficiencies, safety considerations, cost analysis, regulatory compliance..

**D3.2: The plasma journey from collection to transport to fractionator – Recommendations for Improvement**

The most efficient and secure way to manage the plasma collection and processing chain is development and application of European good practices and cooperation between blood establishments and professionals at the European level.

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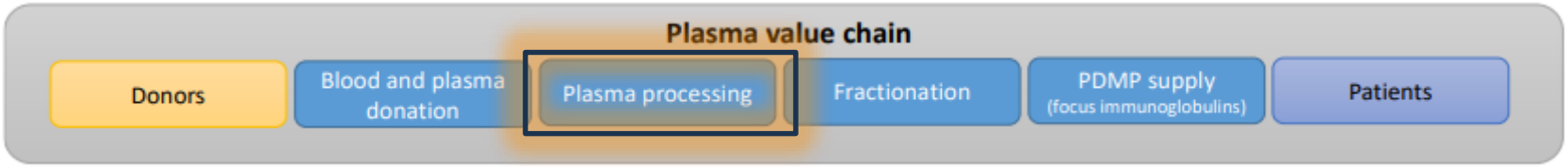


# D3.3: Opportunities to increase Plasma volumes: Recovered and via plasmapheresis: Analysis and Recommendations

## Political recommendations

### 1. To increase plasmapheresis in the public sector

a) Government pragmatic support is needed.

b) Implement actions and regular national campaigns for plasmapheresis

c) Implement a System of Plasma Collection Accreditation unified at EU level for the public sector

d) Work on transforming first time donors into loyal plasmapheresis donors

### 2. Simplification and modification of regulatory requirements

a) Acceptance criteria and testing requirements defined for PfF

b) EU acceptance of IRL and UK plasma

c) Authorisation for mobile sites collecting plasmapheresis plasma

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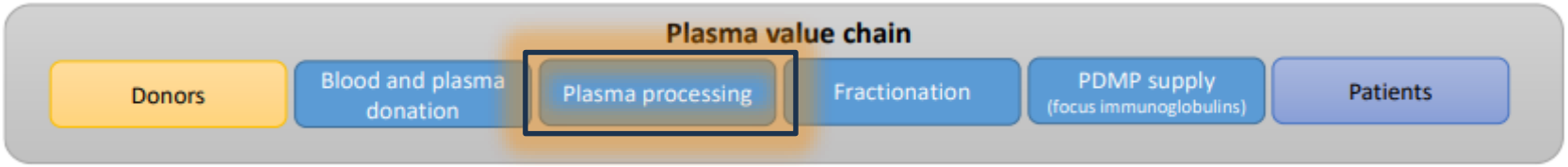


# D3.3: Opportunities to increase Plasma volumes: Recovered and via plasmapheresis: Analysis and Recommendations

## Practical recommendations

1. Improve Whole Blood recovered plasma yield
2. Implement Plasmapheresis collection in all Blood Eestablishments
3. For apheresis plasma, use bottle containers
4. Move from 100% plasma platelets to 30% plasma platelets
5. Increase frequency of Plasmapheresis donations within donor protection guidelines (see WP5)

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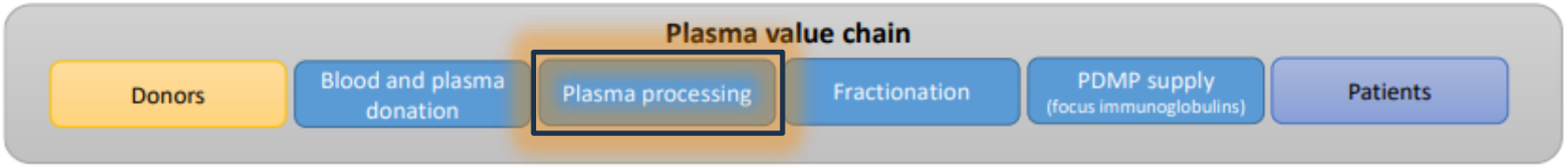


## D3.6: ‘Focus on quality: An assessment of plasma donor characteristics, Immunoglobulin, and Total Protein in donated plasma’

- IgG concentration has an impact on the yield during fractionation.
- Different donation frequencies influence the yield of IgG from pools.
- IgG content in source pools with different backgrounds in donation frequency can differ by over 10%.
- Plasma donations of “low-frequency” donors have a higher concentration of IgG.
- Regarding total sum of IgG donated per month, “high-frequency” donors still donate a multiple of donors with lower donation frequency.

**The recommendation is to use the IgG concentration to determine the value of plasma.**

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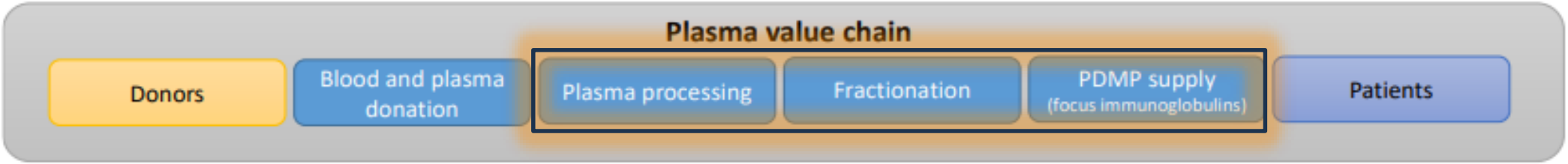
# SUPPLY

## Work Package 4

# National and EU infrastructures / policy/legal framework for plasma collection and PDMPs supply

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| Deliverable | Report |
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| D1.1 | Crisis Situations – The impact on the plasma-medicine-patient chain: Analysis and Recommendations (Scenario Evaluation Plan) |
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| D2.2 | Plasma Donor recruitment and retention strategies – Efficiency evaluation (Recommendations Report and Transfer Plan) |
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| D3.4 | Real-world experience: Implementation of the recommendations to increase Plasma volumes |
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| D4.4 | Member State steps on the European path to Strategic Independence for Plasma Medicines: A Position Paper |
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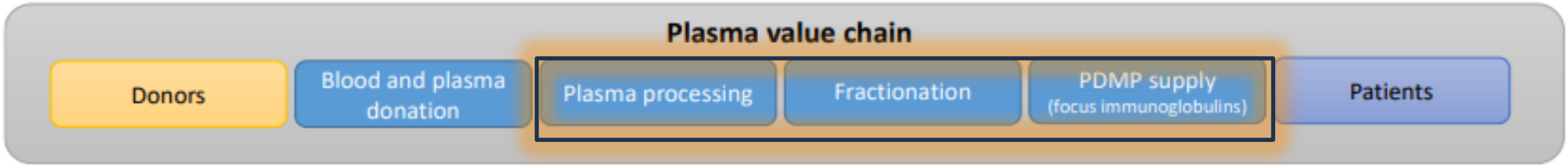


**WP4: National and EU infrastructures/policy/legal framework for plasma collection and PDMPs supply**

Most important recommendations

## Commitment and Control

- It is of critical importance that national commitments to collect sufficient volumes of plasma are accompanied by sufficient control over the Plasma-PDMP-Patient chain, ideally through legislative guarantees, to ensure that the patient population needs are met

## Define plasma as a strategic resource

- Adopt a common legislative framework in the EU in terms of principles aimed at defining plasma as a strategic resource for European citizens
- These should be supported by recommendations at national level for the priority use of PDMPs coming from national plasma, which should be made available for the therapeutic benefit of the EU patients in the first place

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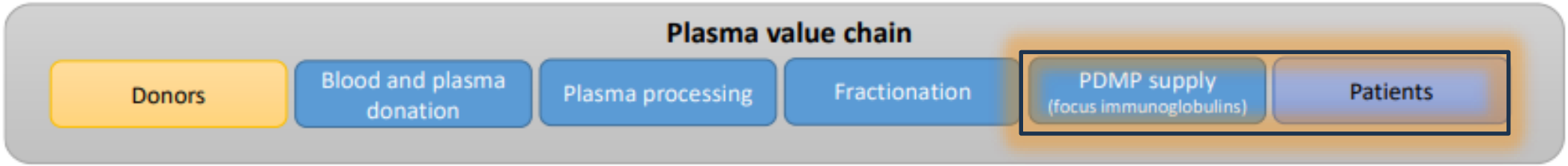
SUPPLY

# Work Package 6
# Clinical Programme on appropriate/prioritised use of PDMPs

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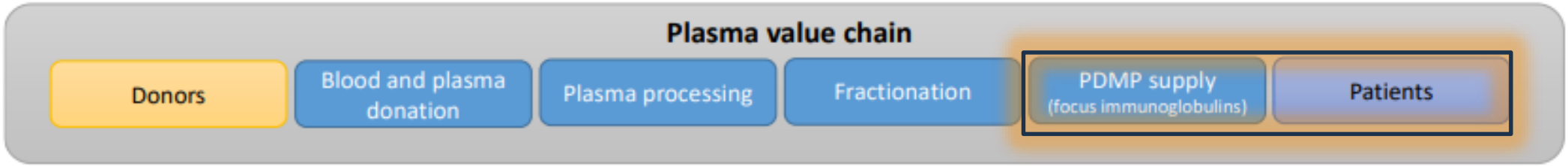


## WP6 Recommendations

**Objective:** Improving Ig use and healthcare outcomes for patients in need of Ig in the EU.

**Improved Understanding of Ig Usage:**

- Create a comprehensive national database in each Member State.
- Include, at a minimum, information on Ig use at a granular patient level.
- Share information in a structured manner to establish consistent indications across all EU Member States

**Structured Management Plan for Shortages:**

- Develop a harmonised European prioritisation plan methodology.
- Utilise a common backbone adaptable to each country's organization, epidemiology, and resources.
- Implement a harmonised approach for managing Ig use across Europe.
- Establish Europe-wide communication and shortage awareness systems.

**Enhanced Collaboration and Linkages:**

- Assess opportunities to build on existing initiatives.
- Collaborate with relevant stakeholders and expert networks.
- Ensure linkages between similar initiatives for optimal synergy.

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# SUPPLY - Part of a continuum..

Critical Medicines Alliance

Critical Medicines Alliance

EGALITE

European Group For Accreditation And Liaison Of Blood-Tissues And Cells Establishments

edqm European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

Funded by the European Union and the Council of Europe

EUROPEAN UNION

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Implemented by the Council of Europe

**EDQM & EU Commission**
**Plasma Supply Management Symposium**
**(29-30 January 2019)**

**Recommendations to Stakeholders**

These recommendations were drafted by a working group consisting of members of the TS093 Plasma Supply Management Working Group, a subordinate working group of the European Committee on Blood Transfusion (CD-P-TS), and stakeholders' representatives during a meeting held the day after the Plasma Supply Management Symposium (list of participants as Appendix).


CHESSMEN

Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network

Public Health

Home > Medicinal products > A pharmaceutical strategy for Europe > Reform of the EU pharmac

## Reform of the EU pharmaceutical legislation

EUROPEAN COMMISSION

Brussels, 24.10.2023
COM(2023) 672 final

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS**

**Addressing medicine shortages in the EU**

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicines | Human regulatory | Veterinary regulatory | Committees | News & events | Partners & networks

## EMA takes further steps to address critical shortages of medicines in the EU

Share

News 24/10/2023

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# SUPPLY Project Take aways - Summary

- Focus on retaining donors while building a sustainable donor base
- Carry out a large prospective study in plasma donors to examine the health consequences of plasma donation at varying frequencies
- Take consideration of the IgG level to determine the value of plasma
- Invest in the increase and improvement of the plasma collection, MS create action plans!
- Introduce legal provisions at national level which link collected plasma to the usage of products manufactured from this plasma by the public health sector
- Important to prioritise both donor *and* patient health
- Create national databases on Ig usage at patient level
- Need for an EU wide harmonized management plan on shortages
- Continue to collaborate!

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# Thank You

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# Thank you

## Questions / Comments/ More Information :

- Website: www.supply-project.eu
- E-mail: info@supply-project.eu
  info@europeanbloodalliance.eu

# Spare Slides