

Transfusio eta Giza Ehunen Euskal Zentroa: 40 urte odol eta ehunen segurtasuna bermatzen

The Basque Blood
Establishment: 40 years of
blood and tissue safety

Laura Biritxinaga
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Osakidetza

TRANSFUSIO ETA GIZA EHUNEN
EUSKAL ZENTROA
CENTRO VASCO
DE TRANSFUSIÓN Y TEJIDOS HUMANOS



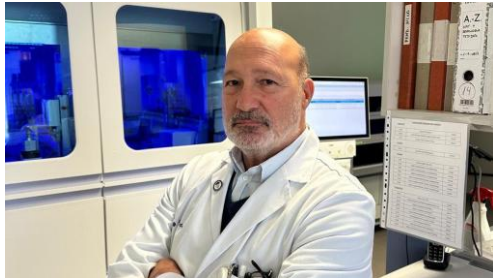
EUSKO JAURLARITZA
GOBIERNO VASCO



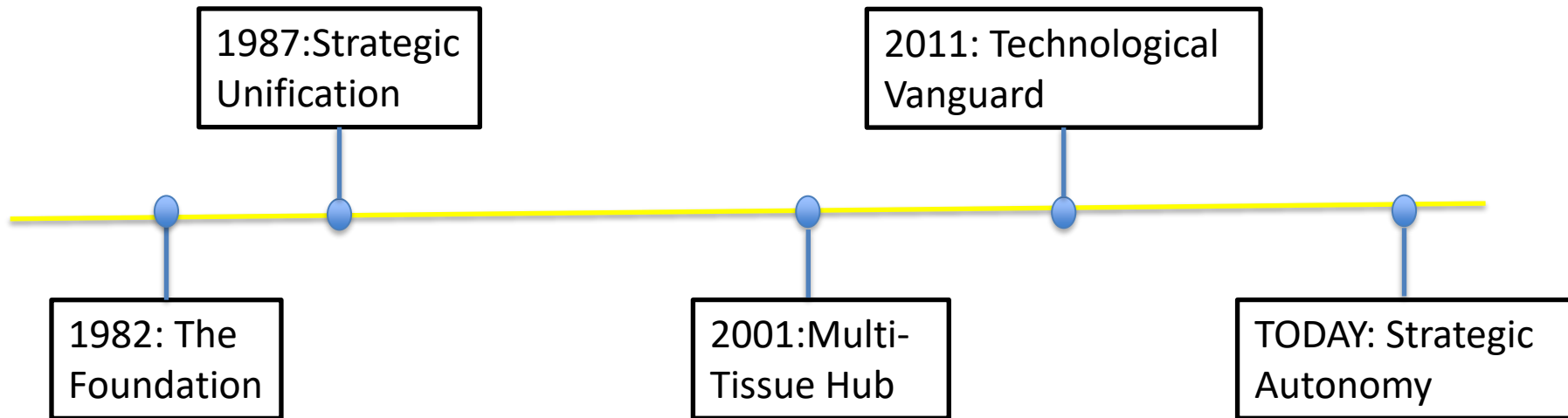
Disclosure

- *The author has no conflicts of interest to disclose*

40 Years of Blood & Tissue Safety in Euskadi: A Local Perspective



Dr. Miguel Ángel Vesga



Operational Excellence: Serving the Entire Healthcare System

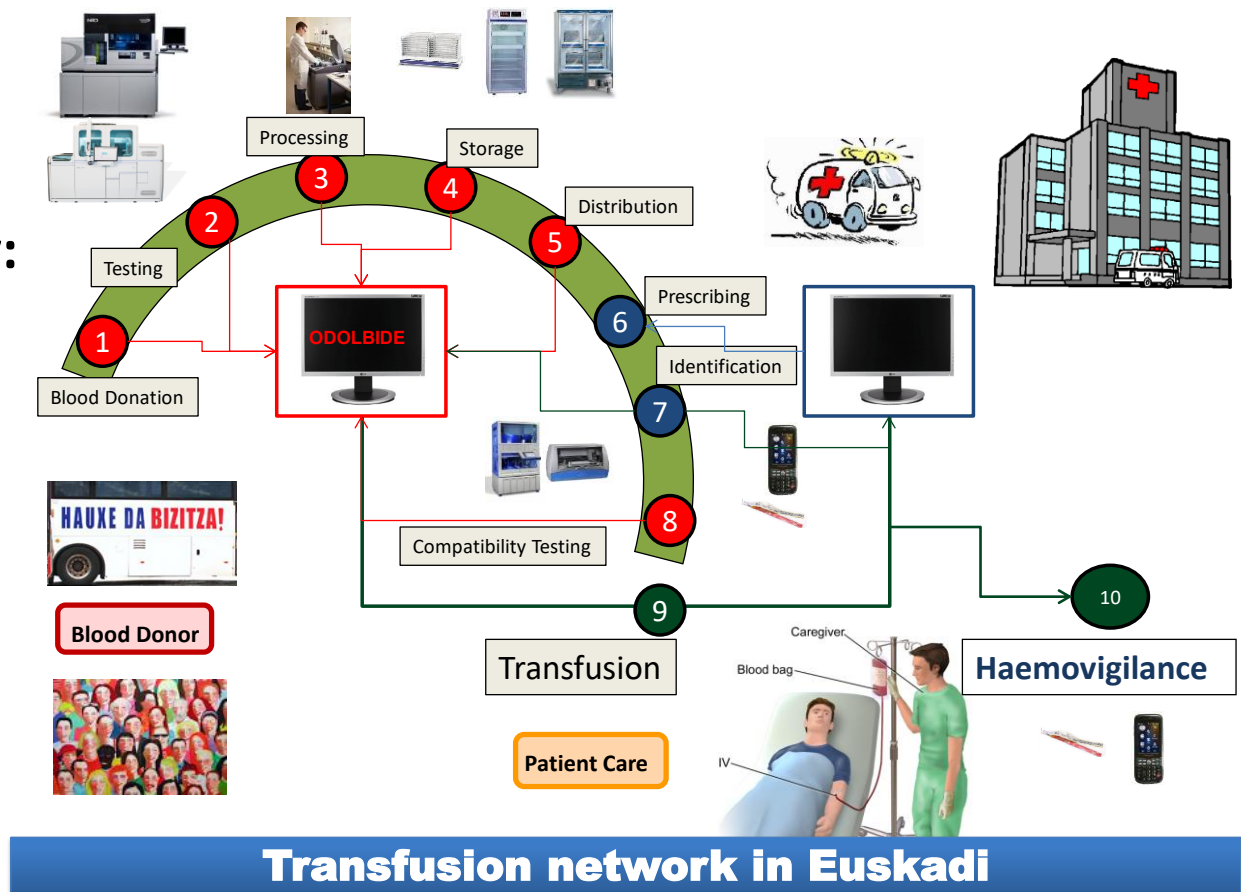
- **Population 2.2 million**
(Osakidetza - Basque Public Health Service)
- **Annual Blood Activity:**
 - Over 90,000 whole blood donations
 - Platelet and Plasma apheresis programs
- **Comprehensive Tissue Bank:**
HSC · Cornea · Bone · Tendons · Vascular · Nervous · Skin
- **A Universal Service:** 100% Publicly managed, supplying over 50 public and private hospitals in the region



Flysch, Zumaia, Gipuzkoa

Full System Integration: Traceability & Connectivity

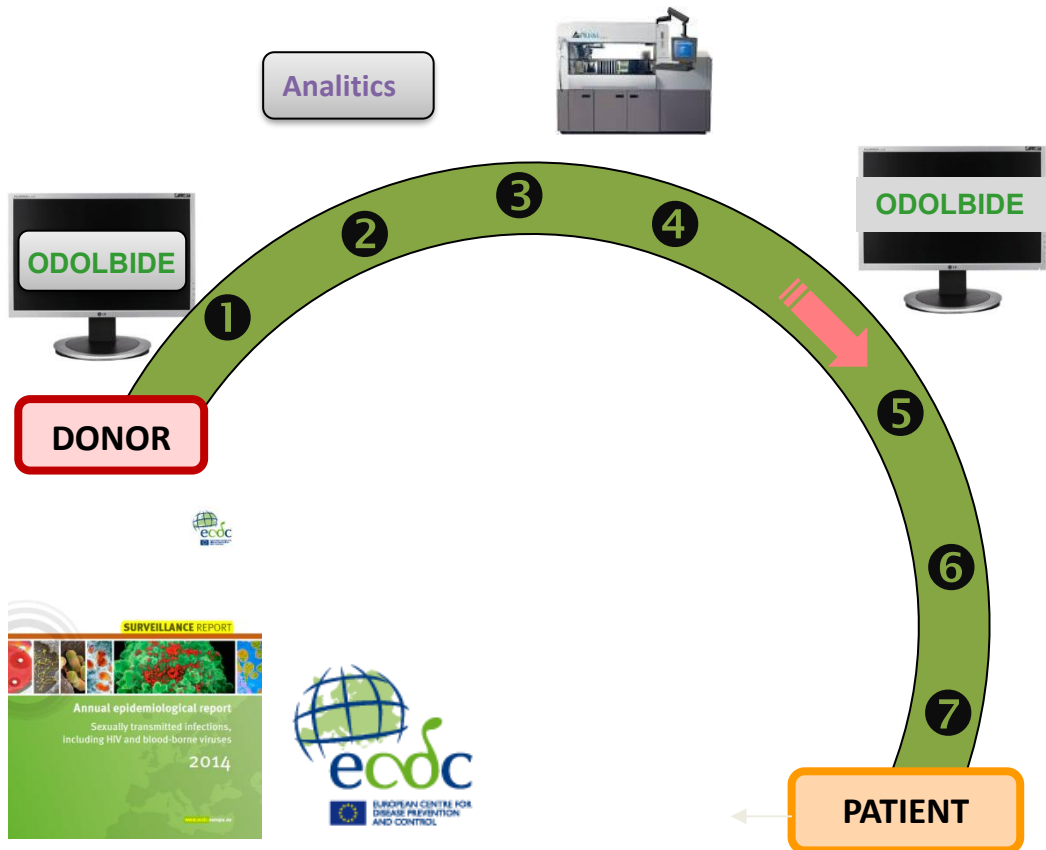
- **Unified Network:** Real-time data sharing across all regional nodes
- **Digital Traceability:** 100% "Donor-to-Recipient" tracking for blood and tissues
- **Efficiency:** Centralized decision-making supported by integrated IT platforms



Transfusion network in Euskadi

Blood Transfusion

Microbiological Safety: High-Sensitivity Screening



Serological Tests

- HIV, HCV, HBV (including Anti-HBc), and CMV
- Syphilis, HTLV-I/II, Chagas Disease, and Malaria

Molecular Tests (Single donation)

- HIV, HBV, HCV, WNV, and Chikungunya?

Blood Banking & Transfusion Medicine

- ABO-Rh Blood Grouping, IH Typing, HLA Typing, Phenotyping, and Genotyping
- (Platelet inactivation)

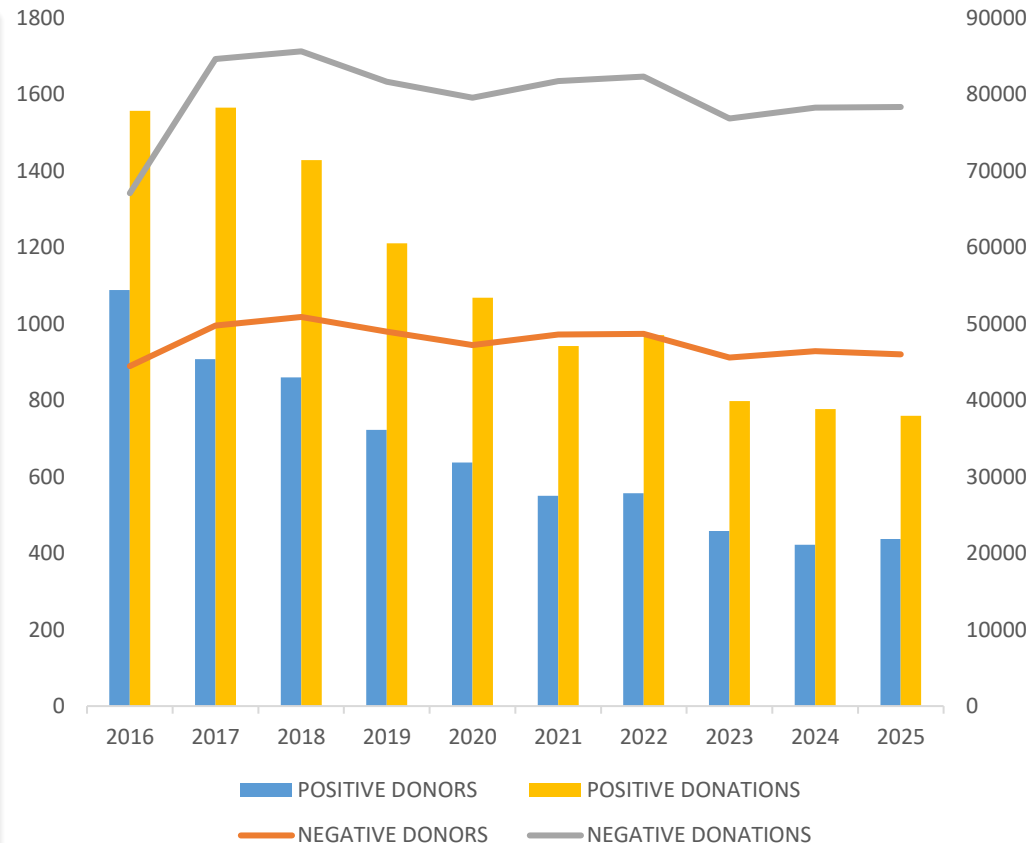
SUFFICIENCY



SAFETY

Surveillance: Universal anti-HBc Screening: Balance & Strategy

- **Universal Implementation (2016):**
 - Initial epidemiological data revealed **2.6%** core-positive donors
 - *Context:* Universal childhood vaccination in Spain started in the 80s
- **The Sustainability Challenge:**
 - Immediate exclusion of all core-positive donors threatened supply
- **Targeted Safety Protocol:**
 - Implemented a threshold strategy: Deferral only if anti-HBs <100 IU/L
 - This tactical approach reduced immediate donor loss to just **1.7%**
- **Progressive and strategic decrease of core-positive donors over time**
 - Successfully secured both safety and sufficiency



Microbiology & Surveillance: Emerging & Imported Threats

- **WNV Individual NAT:**

Implemented to avoid donor exclusions and protect summer sufficiency

- **30-Day Frozen Storage:**

for rapid stock release in case of local outbreaks

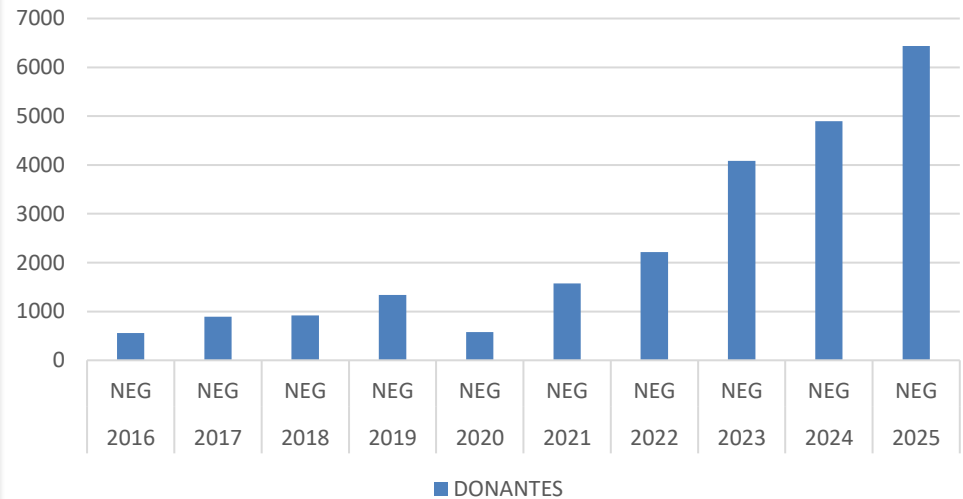
- **Border Vigilance:**

Chikungunya human cases already detected near our biggest cities

- **Territorial Risk Profile:**

Small, highly dense populated region

DONORS



Vector: *Culex pipiens*



The Spanish Transfusion System: A Collaborative Model



- Shared governance between the Ministry of Health and Regional Health Services
 - Political and regional alignment through the **National Commission for Hemotherapy** (CNSyE)
- Technical & Scientific Harmonization: Medical guidelines driven by the Scientific Committee for Blood Safety

Sistema Nacional para la Seguridad Transfusional

Comisión Nacional de Hemoterapia

CC ST COMITÉ CIENTÍFICO SEGURIDAD TRANSFUSIONAL

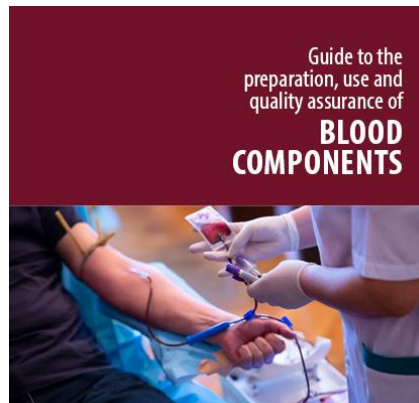


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Comisiones autonómicas



Strict compliance with EDQM Guidelines
The European Gold Standard



European Committee on Blood Transfusion (Partial Agreement) (CD-P-TS) 2025



- Non-Negotiable:
100% Voluntary and non-remunerated
Focus on strategic **self-sufficiency**



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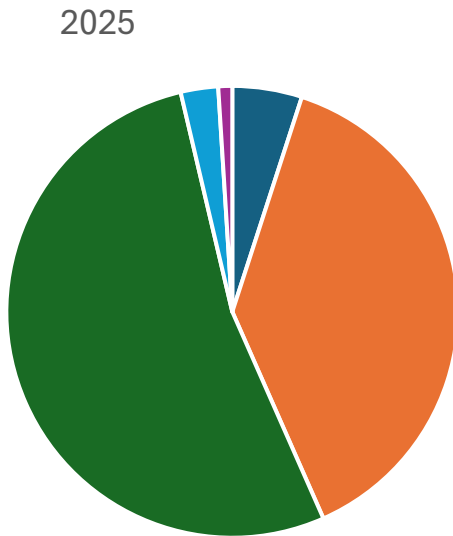
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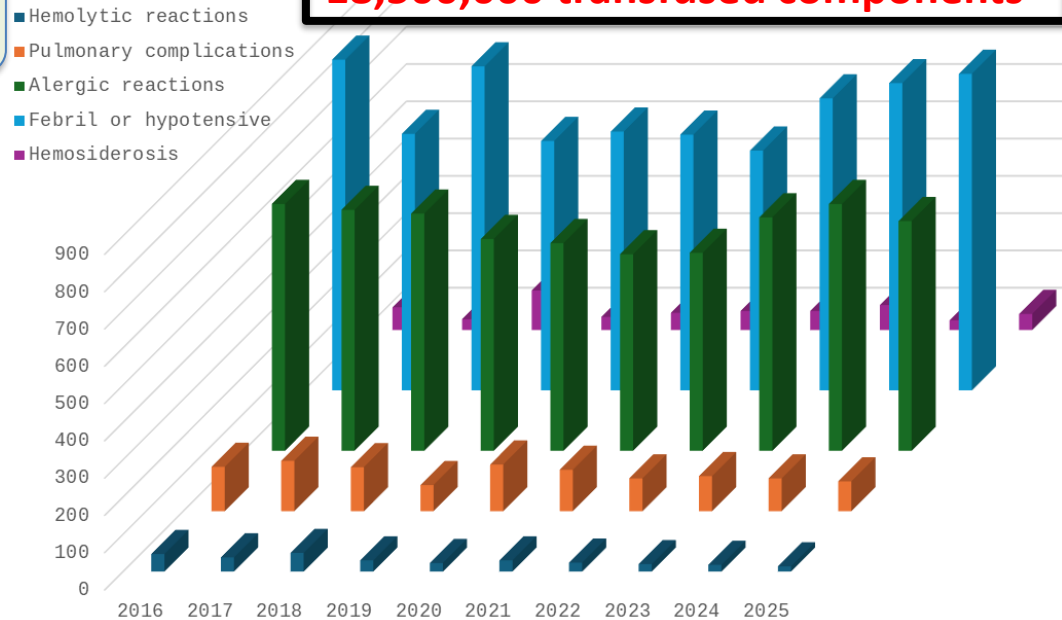
National Hemovigilance Overview

Protecting a population of 49.6 million people across Spain

- Pulmonary complications
- Allergic reactions
- Febril or hypotensive reactions
- Hemosiderosis
- Others



18,500,000 transfused components



Source: National Hemovigilance Report, Ministry of Health

- High reporting culture across all regions.
- **Extremely low** incidence of **severe** transfusion-transmitted infections (4 viral)
- Total traceability and rapid response capacity

The New Regulatory Era: SoHO Division

- REGULATION (EU) 2024/1938 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application
 - The SoHO Regulation officially entered into force on August 6, 2024.
 - EU Member States have until August 7, 2027, to fully apply the new rules.
 - Enhancing **protection for donors and recipient**
 - Fostering **innovation and technical excellence**
 - Ensuring **high standards** for all substances of human origin
- A National Milestone to support this: creation of a dedicated **SoHO Division** within the Ministry of Health
- Strategic Role: Leading the transition towards a more **harmonized** European landscape



SoHO Regulation

Spanish agreement on national plasma fractionation



1. PUBLIC TENDER (Spanish Ministry of Health, technically supported by /Spanish Committee for Blood Safety and Sufficiency and Experts from Blood Establishments).
Date of award and signature. March, 2025: AWARDED COMPANY: GRIFOLS

2. DURATION: 2 YEARS + 2 YEARS (2025-2029). MANDATORY FOR ALL AUTONOMOUS COMMUNITIES

Economic Efficiency: Overall tender value of **€281 million**.

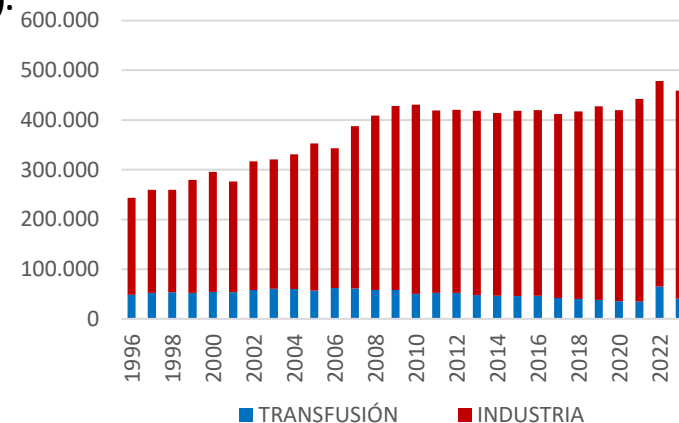
System Savings: Estimated savings of **€71.8 million** for the total 4-year period (including optional extensions)

3. ESTIMATED MINIMUM VOLUME OF PLASMA / FIRST YEAR: 450.000 L (SOURCE PLASMA AND WHOLE BLOOD). PDMPs INVOLVED: ALBUMIN, IMMUNOGLOBULINS, FACTOR VIII, FACTOR IX, ALFA1-ANTITRYPSIN, ANTITHROMBIN III

4. PROCEDURE SUMMARY:

- Plasma collected is picked up by the awarded company at the Blood Establishments and sent to the facilities of the fractionation industry according to the defined program
- After each fractionation established in the scheduled calendar, BE receive the products obtained in relation to the amount of plasma provided by each of them. BEs distribute these PDMPs to hospitals under their influence

Plasma destination, Spain



Transfusion: 9% Fractionation: 91%

Historical Safety Track Record (Since 1980s):

- Plasma primarily dedicated to industrial fractionation.
- Zero confirmed viral transmissions or severe safety alerts in 40 years

Conclusion: Balance and Future Outlook

- 40 Years of Evolution: A continuous journey of adaptation and safety
- Strong Regional Identity: A public system fully integrated into a robust national framework
- Future-Ready: Prepared to lead the new emerging and regulatory eras (SoHO)



- Strategic Autonomy: Ensuring long-term supply and patient care
- Social Engagement: Built on the commitment of our voluntary donors

Eskerrik asko
Thank you very much

Our Demographic challenge

- Exceptionally high life expectancy in the region **81.7 years for men** and **87.0 years for women**
- 100% Self-sufficiency in blood components successfully guaranteed across the region
- ***Strategic Outlook: Proactive policies to secure long-term sustainability and supply.***

