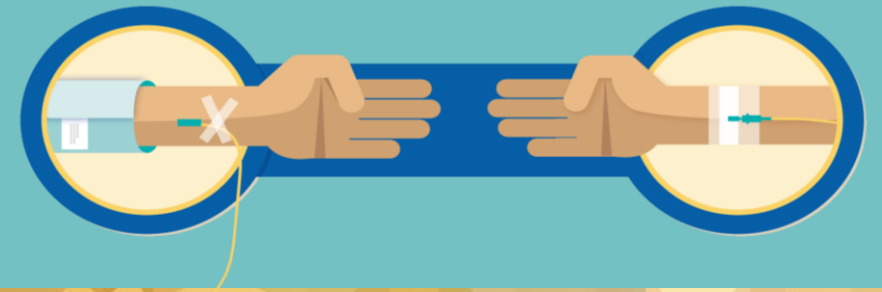


# PLASMA SUPPLY AND PLASMA- DERIVED MEDICINAL PRODUCTS MANUFACTURING

Maarten Van Baelen, Executive Director PPTA

29 April 2022

Rome, Italy



# Socio-Economic Value: Optimal PDMP treatments alleviate patients' disease burden and translate into health value of recovered life-years

## HEALTH GAINS AND AVOIDABLE HEALTHCARE COSTS (PID & HAEMOPHILIA IN EUROPE)

### PID ≈ 1 Bn €/year

PDMP eligible population in Europe: ~44,000  
Survival rate 1979 = 30 % vs. 2010 = ~100%  
65% reduction in infections



AVOIDABLE  
HEALTHCARE COSTS  
1.1-1.6 Bn €/year

PDMP eligible population in Europe: ~47,000  
Life expectancy prior 1955 = 19 years vs. 2001 = 71 years  
80% reduction in bleeds

Haemophilia ≥ 1 Bn €/year

Limiting access to PDMPs often equates with denying Patient Access to the only effective therapy and reduces the concomitant socio-economic benefits.

## HEALTH GAINS AND AVOIDABLE HEALTHCARE COSTS CALCULATION

### CALCULATIONS INPUTS

- Health Gain = Recovered DALY \* VOLY
- DALY is the sum of the Years of Life Lost (YLL) due to premature death and the Years Lost due to Disability (YLD)
- Key DALY component for PID is # of severe infections per year and for Haemophilia: key DALY component is 3 of bleeds per year
- VOLY (Value of a Statistical Life Year) is estimated at €40,000
- Avoidable indirect healthcare costs for PID based on reduction of hospitalization days due to severe infection

# EU countries have an increasing need for plasma-derived medicines



- While current demand for blood components for transfusion is decreasing.
- Demand for plasma derived medicines has increased by 8% yearly over the past decade.

(Source: European Commission survey, 2014; Marketing Research Bureau)

# The EU's growing patient population for plasma for medicines

PER PATIENT PER YEAR:

MORE THAN  
**1200:**  Plasma donations to treat  
**ONE PATIENT** for HEMOPHILIA.

MORE THAN  
**900:**  Plasma donations to treat  
**ONE ALPHA-1 PATIENT.**

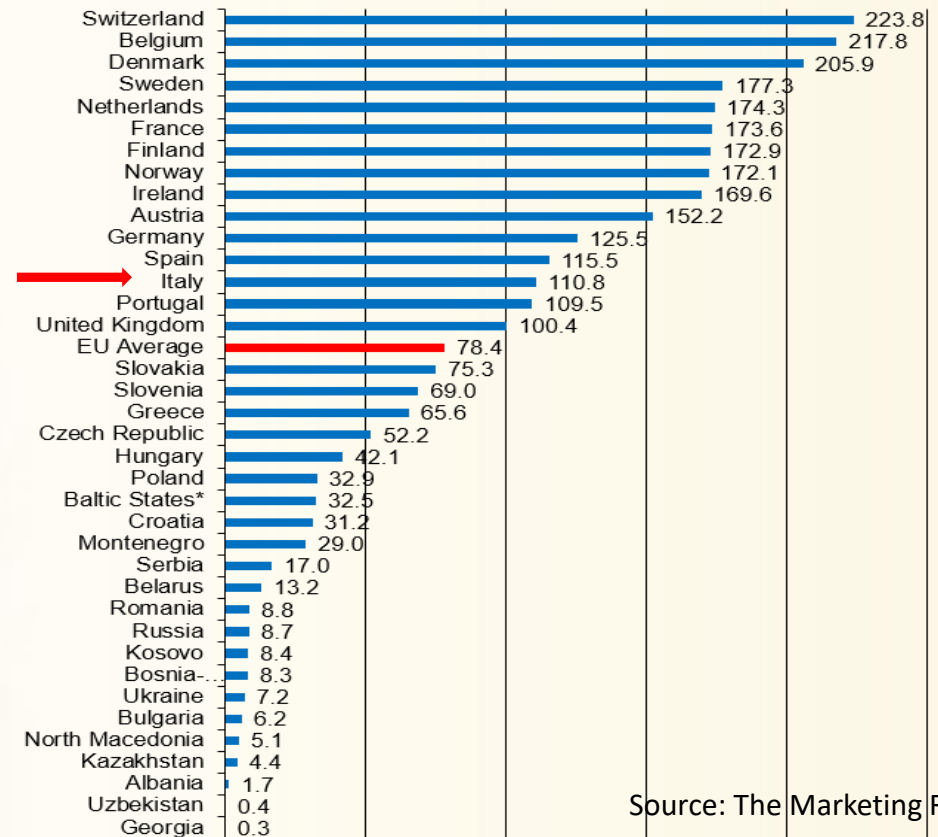
MORE THAN  
**130:**  Plasma donations to treat  
**ONE PATIENT** with a  
**PRIMARY IMMUNE DEFICIENCY.**

- **More precise medical diagnostics** open plasma-derived medicines to more people.
- **More clinical evidence** of the benefits of plasma-derived therapies.
- **Patients are living longer.**

# Health inequalities between countries

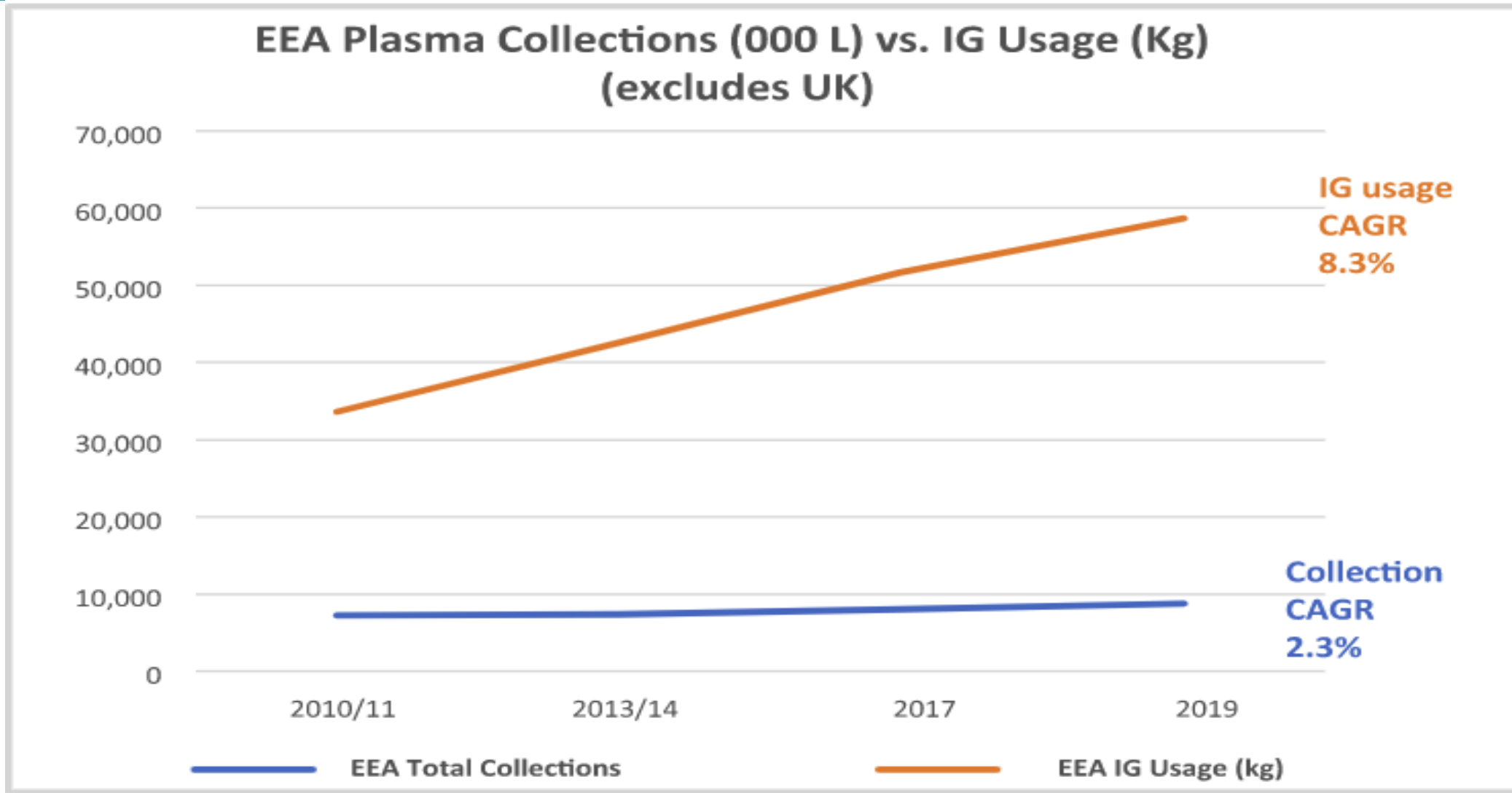


**AVERAGE IG CONSUMPTION BY COUNTRY - 2020**  
(Kilograms per Million Population)



Source: The Marketing Research Bureau

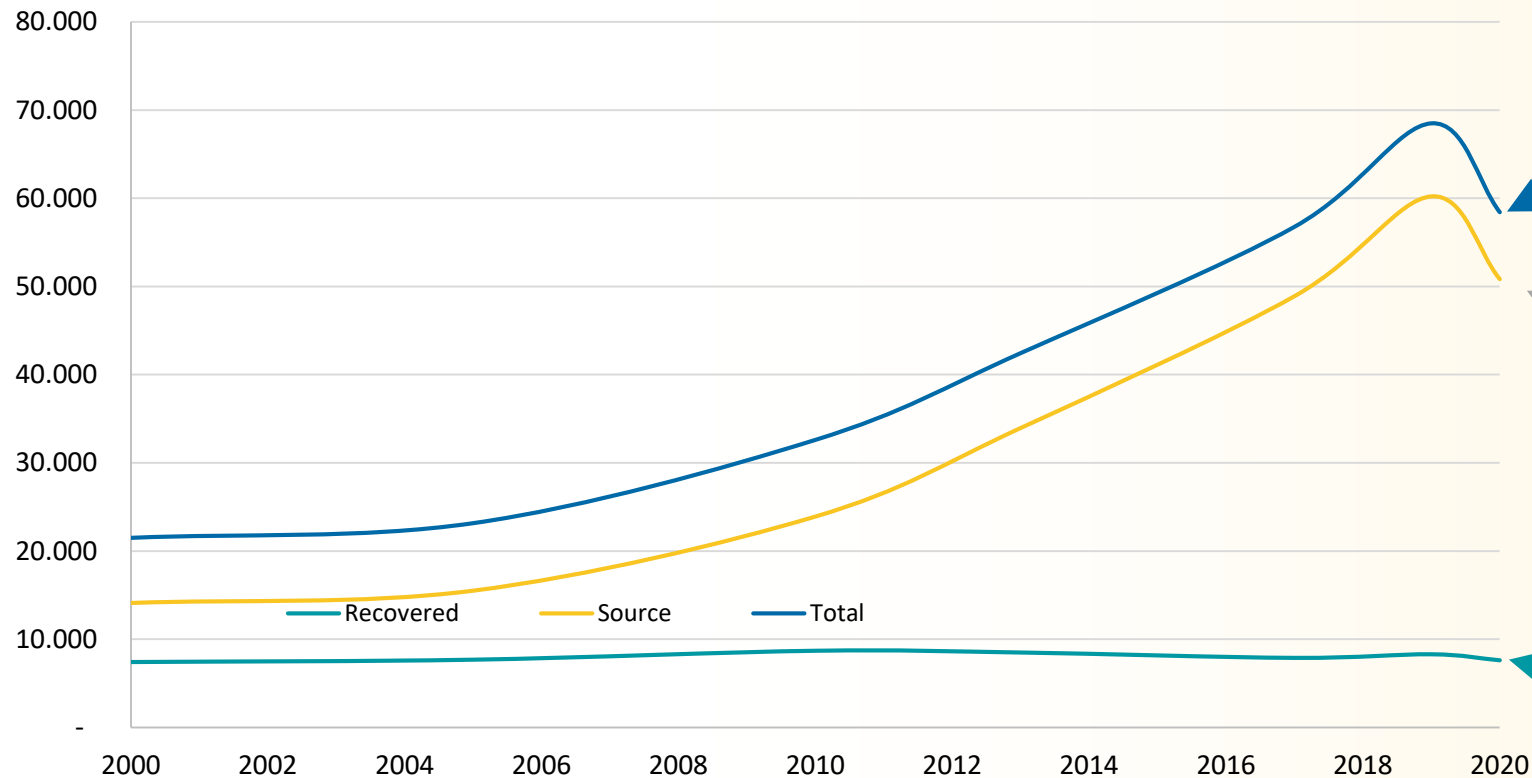
# European plasma & donation trends: public vs private collection





# Global plasma for fractionation

**Global Plasma for Fractionation  
(Liters X 000)**

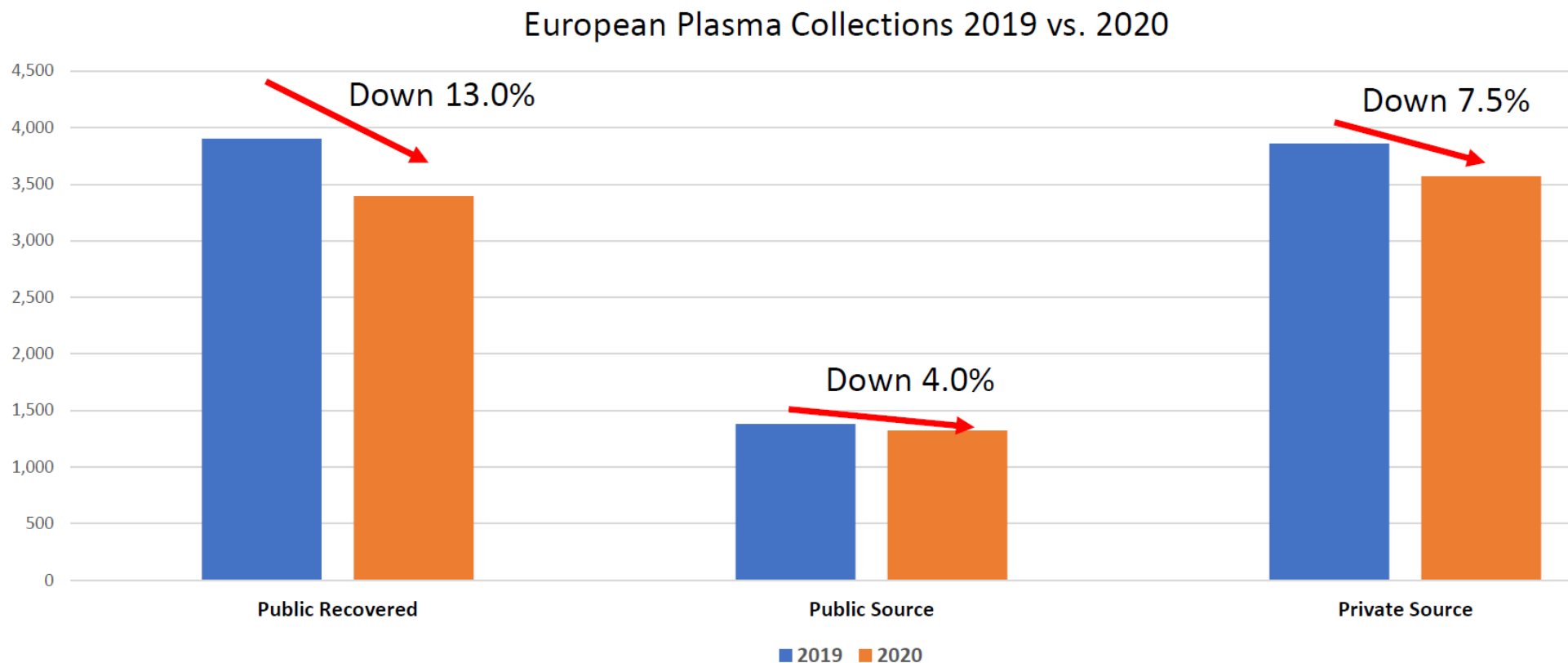


Total plasma fell 14% in 2020 due to COVID19 pandemic

All growth in plasma for fractionation has come from Source (Apheresis) plasma (mainly private), but COVID pandemic dropped it significantly

No growth for Recovered plasma (all public). Slow decline in recent years, including during COVID pandemic.

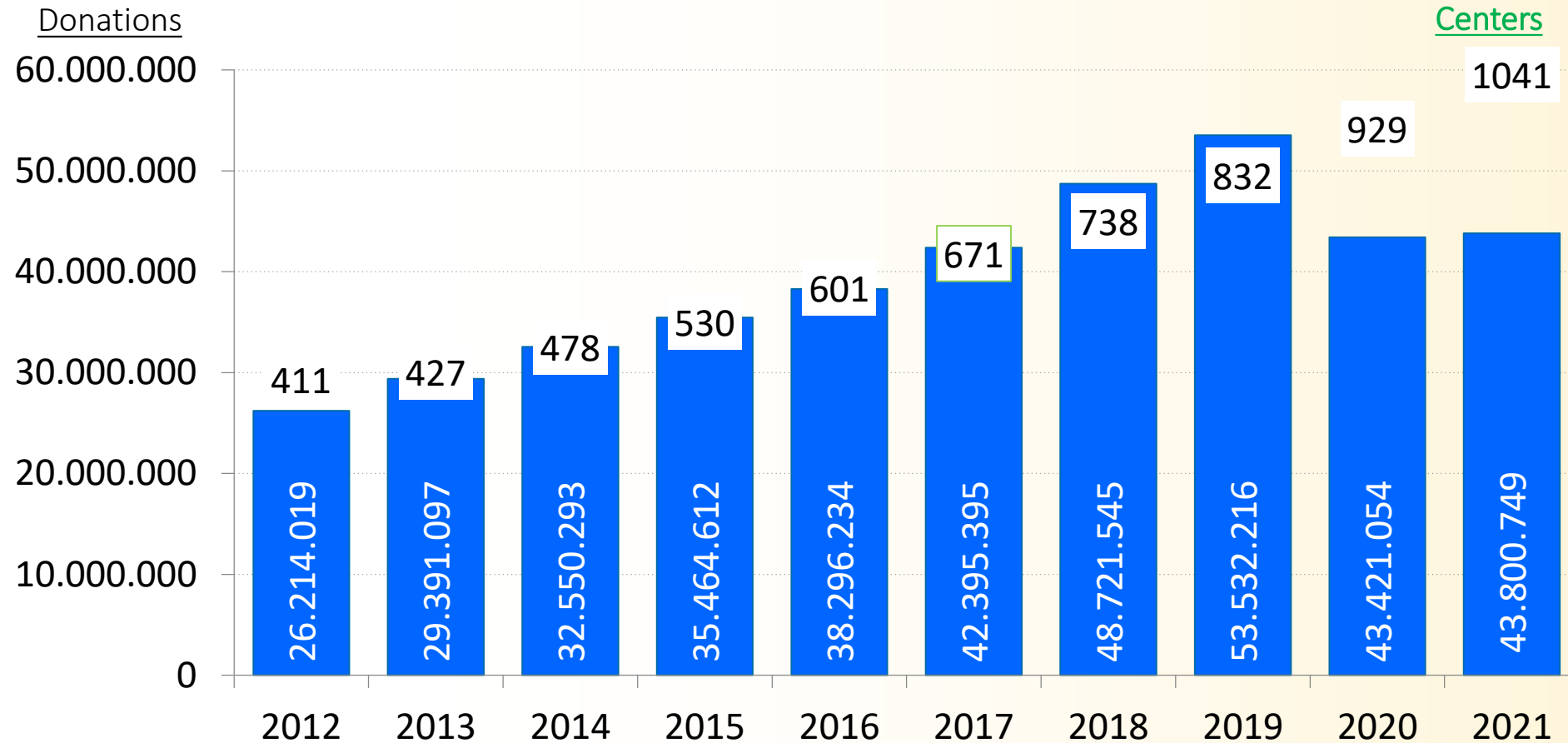
# European Plasma Collections by Type – COVID impact



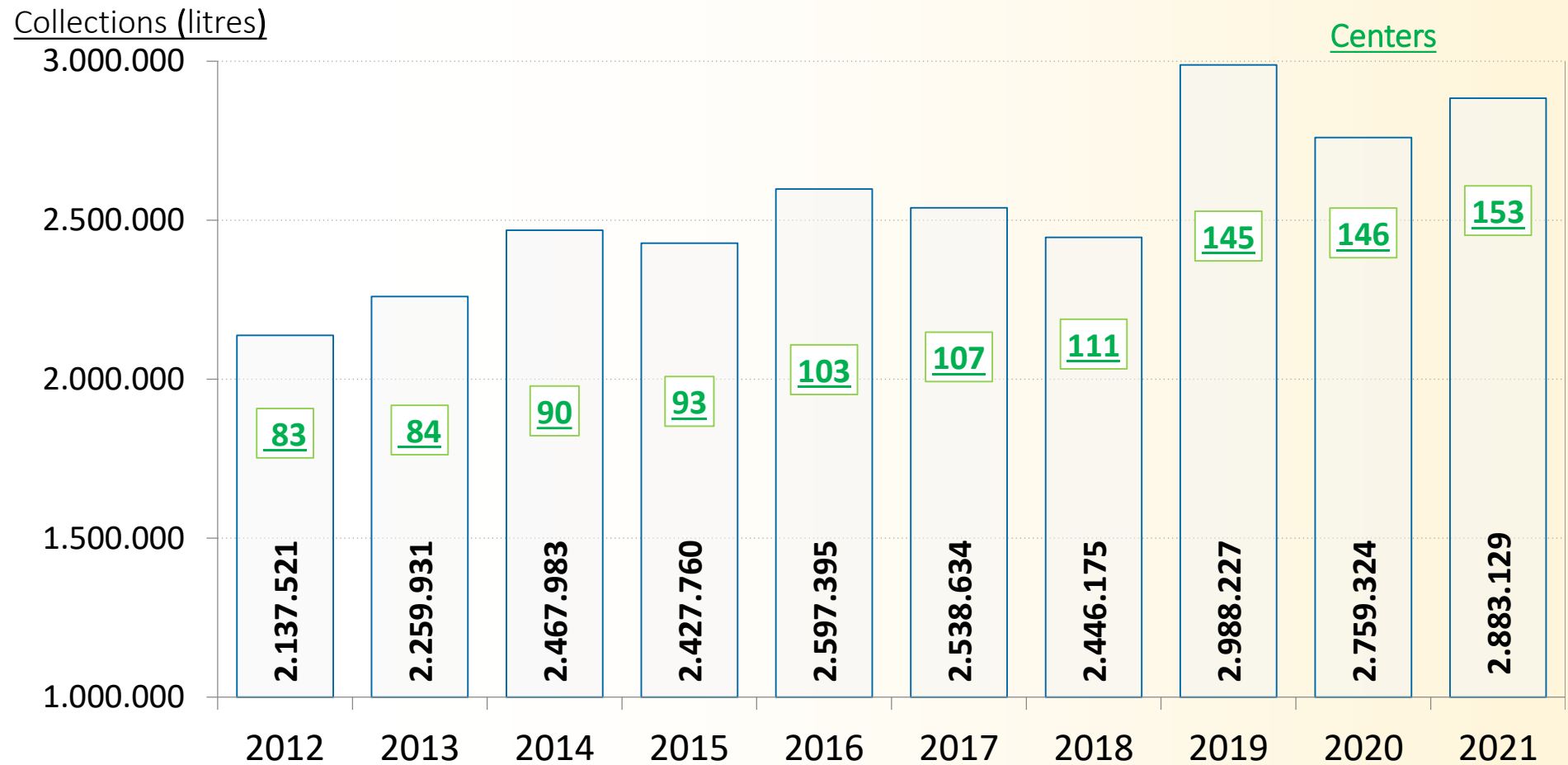
Overall European collections declined by 9.4% in 2020 vs. 2019 due to the pandemic.  
In 2020, a total of 8.3 million liters of plasma were collected (source and recovered) in Europe.



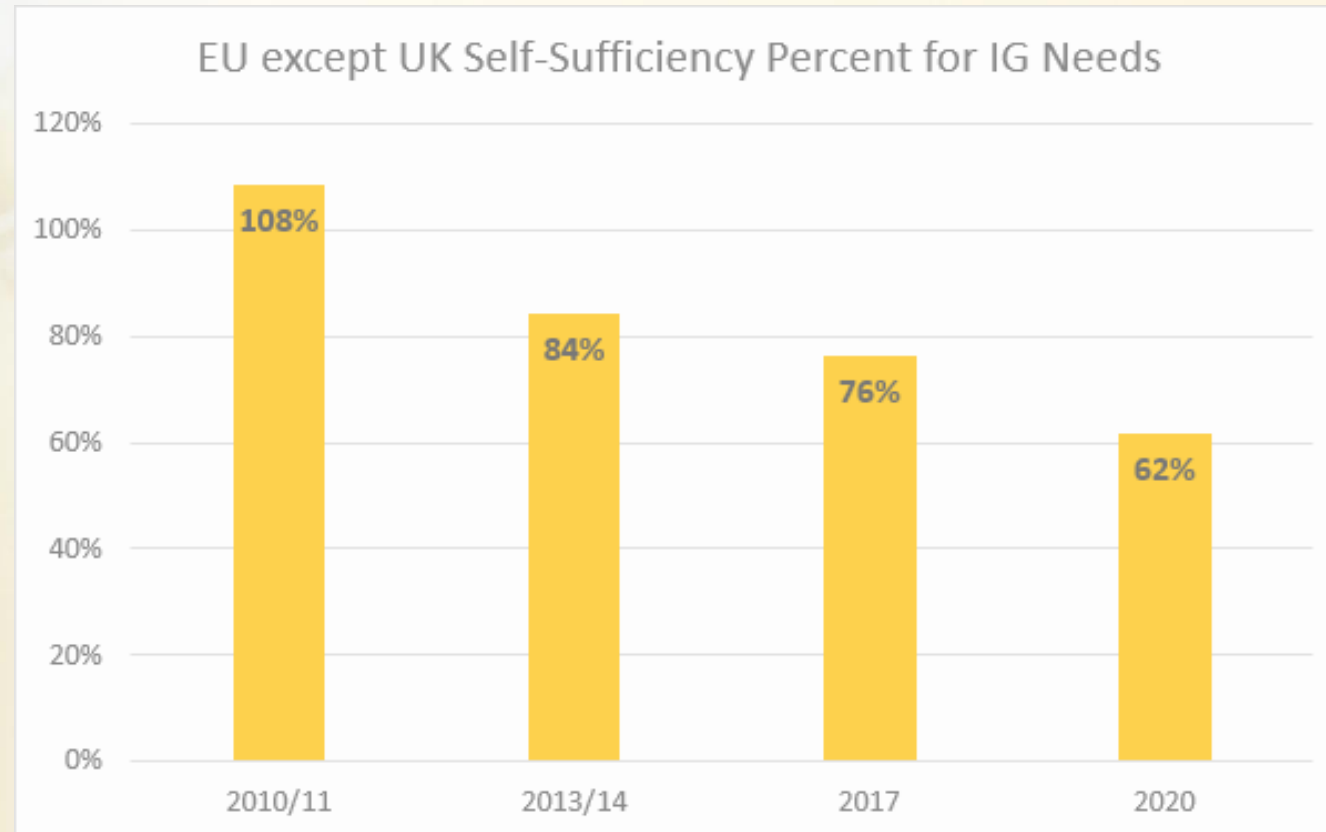
# North America plasma collections by PPTA members



# Europe plasma collections by EPA members



# Self-sufficiency? EU dependency on US: 38% (2020)

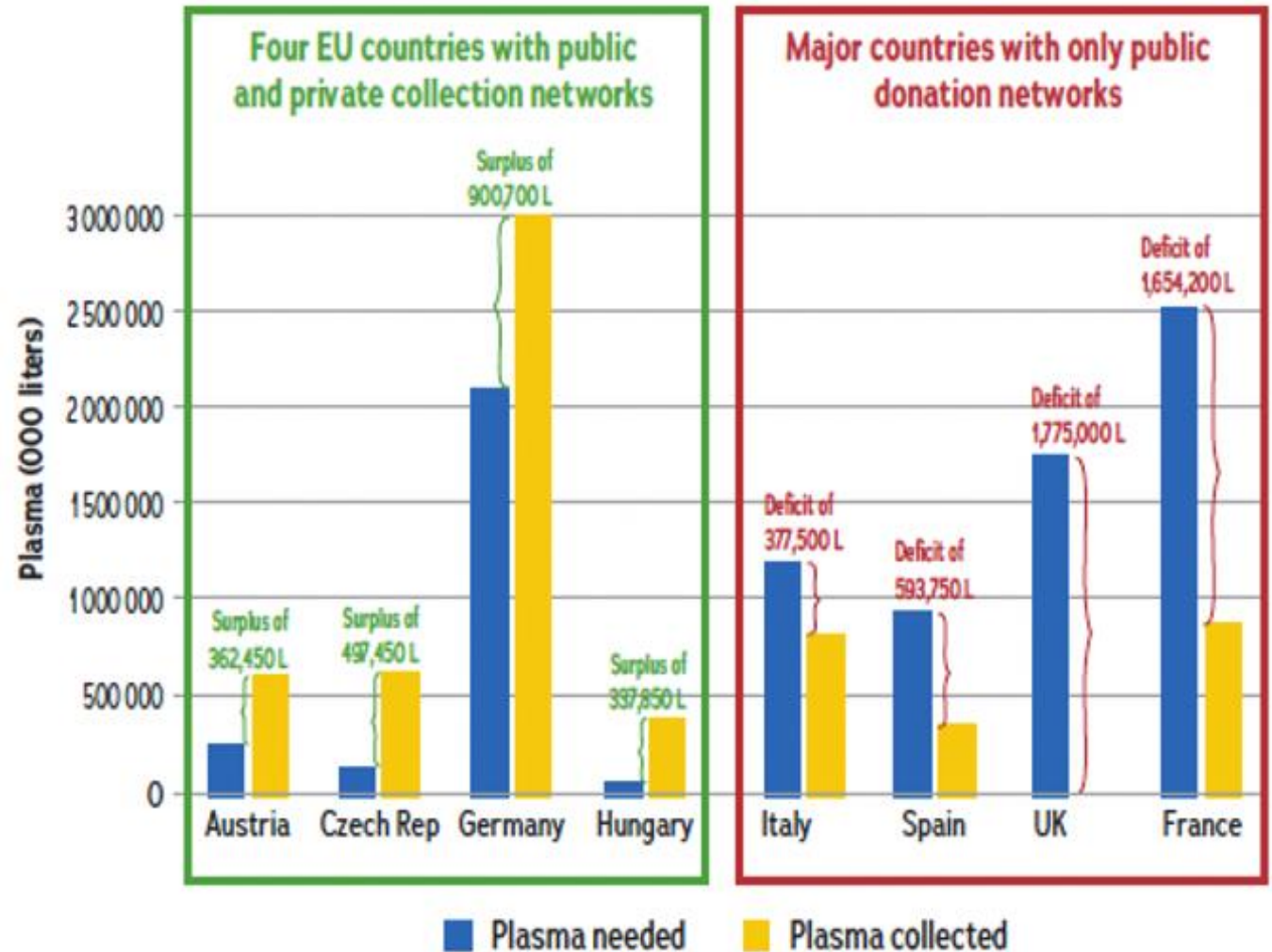


Source: The Marketing Research Bureau

# The EU's plasma donation shortfall

Today, Europe has a shortfall of 38% (or 5,15 million liters) of source plasma needed to produce plasma-derived medicines.

(Source: Marketing Research Bureau, 2021)



# Europe's biggest plasma contributors

## Fact

Austria, Czech Republic, Germany & Hungary contribute 25% of all plasma needed for EU patients.

38% comes from US





# How to collect more plasma in the EU?





# Two ways to donate plasma

**Most efficient**

**Fact**

	Extraction	Donation	Frequency	Duration	Volume
SOURCE PLASMA	<p><b>Donor Center</b></p> <p><b>Blood</b></p> <p><b>Plasma</b> <i>direct plasma donation</i></p> <p><b>Red cells</b></p> <p><i>Used for making plasma-derived medicines</i></p>	<p><b>Plasma</b> <i>plasmapheresis</i></p>	<p><b>1 x weekly</b></p>	<p><b>90 min</b></p>	<p><b>~820ml</b></p>
RECOVERED PLASMA	<p><b>Donor Center</b> → <b>Processing Center</b></p> <p><b>Blood</b></p> <p><b>Plasma</b> <i>For hospital use (transfusion) + making plasma-derived medicines</i></p> <p><b>Red cells</b> <i>Hospital use</i></p>	<p><b>Blood</b> <i>blood donation</i></p>	<p><b>4-6 x yearly</b></p>	<p><b>30 min</b></p>	<p><b>~250ml</b></p>

# Private collection centres in coexistence with public sector: examples from Austria, Czech Republic, Germany & Hungary

Private plasmapheresis donation centres coexist efficiently with public services collecting whole blood and plasma.

- They collect four times more plasma per 1000 inhabitants compared to other countries.

*Source Vintura White Paper: Key economic and value considerations for plasma-derived medicinal products (PDMPs) in Europe. <https://bit.ly/VINTURA>*

- Whole blood donations have not decreased in countries with coexisting donation systems. No crowding out!

*Source: KCE Reports 120A – Hoe zelfvoorziening in stabiele plasmaderivaten voor België verzekeren? 2.1.1: Key points*



# Plasma donation: current compensation practices

Today 25 EU countries provide some form of compensation to plasma donors.

- Covering donors' expenses; recognizing inconveniences related to donating.

**Fact**

In Austria, Czech Republic, Germany and Hungary, private plasma donation centres give fixed-rate allowances in compliance with VUD principle.

**Fact**

Source: The concept of 'fixed-rate' compensation is defined in the DH BIO Interpretation Guide of the Principle of Prohibition of Financial Gain <https://rm.coe.int/guide-for-the-implementation-of-the-principle-of-prohibition-of-financ/16807af9a3>

# PPTA's commitment to health & safety for donors

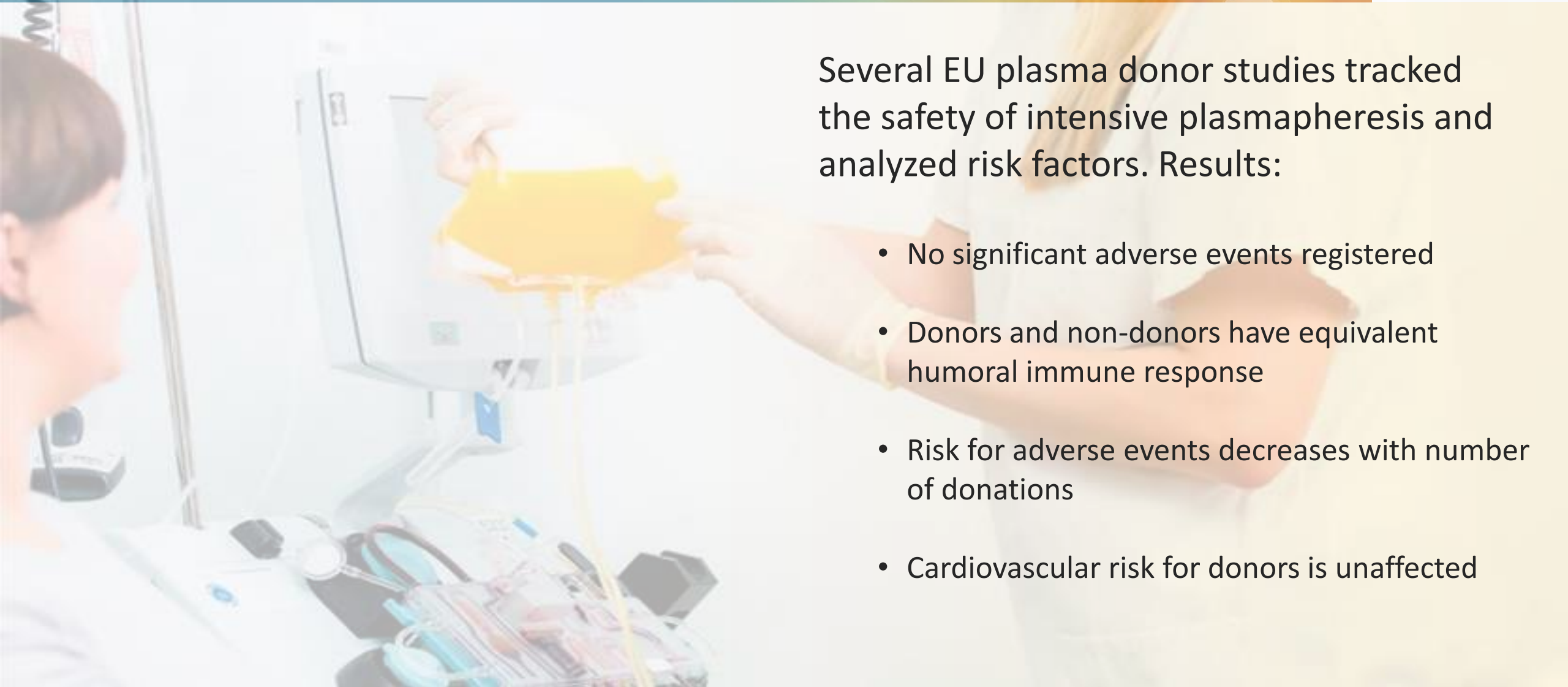


**Plasma donor studies:**  
Tracking & ensuring the safety of intensive plasmapheresis and analyzed risk factors.

# Tracking safety for plasma donors

Several EU plasma donor studies tracked the safety of intensive plasmapheresis and analyzed risk factors. Results:

- No significant adverse events registered
- Donors and non-donors have equivalent humoral immune response
- Risk for adverse events decreases with number of donations
- Cardiovascular risk for donors is unaffected





# Donor safety study data

<b>2016 Data Collection Study Highlights</b>	
Data collection period	3 months in 2016
Total plasma donations	7.6 million (79% of industry)
Dialysis-Associated Encephalopathy (DAE) recorded	15,300
Overall DAE rate	2.09 per 1000 donations
Top 2 DAE Categories 75% of all Adverse Events (AE)	Hypotensive/vasovagal pre faint with no loss of consciousness (57% of all AEs). Local injury (hematoma/bruise) related to phlebotomy (18% of all AEs).
Most rare DAE categories	Severe hypotensive events (0.06 per 1000 donations) Hypotensive events with prolonged loss of consciousness (0.01 per 1000 donations) Hypotensive injury (0.007 per 1000 donations)
<b>2018 Data Collection Study highlights (publication in preparation)</b>	
Data collection period	4 months in 2018
Total plasma donations	12.5 million donations
Overall DAE rate	1.58 per 1000 donations
Top DAE Categories	Vasovagal
Rare occurrences	Medical intervention Donors needing transportation to the hospital within 24 hours, including donors who has AEs after leaving the donation center (0.04 per 1000 donations).



# Toward better access to plasma-derived medicines in Europe

Better for patients

Better for health

Better for society

*[euneedsmoreplasma.com](http://euneedsmoreplasma.com)*

