

Organisation of Blood Services and PDMP Supply in Italy

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Disclosure

I hereby declare that I have neither financial nor non-financial relationships related to any of the products or services described, reviewed, evaluated or compared in this presentation.

Healthcare governance in Italy

Federalist framework since 2001

Delivering healthcare (HC) is delegated to the 21 Regions

6 Autonomous Regions and Provinces with additional autonomy/privileges
(Aosta Valley, Friuli Venezia Giulia, AP Trento, AP Bolzano, Sicily, Sardinia)

Ministry of Health

Responsible for:

- general healthcare legislation
- transposing EU provisions
- defining “basic healthcare levels” (BHCL)
- control of BHCL application in the regions
- control of regional budget balance
- general public health regulation
- Any law / regulation must be preliminarily formally “shared” with regions (State-Regions agreements)¹
- Ministry of Economy strongly conditions the HC national budget (126 billion €, 6.6% of GDP 2022)¹



Principles and social values of the Italian donation system



The Italian Blood System: strategic goals – 1/2

Law 219, 21st October 2005

- **Self-sufficiency** of blood and blood products, including plasma-derived medicinal products (PDMPs) is a national *supra-regional* strategic goal, i.e. independent of the regionalised organisation of health-care delivery.
- **Promotion and continuous development** of voluntary non-remunerated (VNR), regular/repeat blood donation, and VNR donor retention.
- High **quality and safety** of blood components, transfusion medicine activities and PDMPs.

The Italian Blood System: strategic goals – 2/2

Law 219, 21st October 2005

- **Compliance with European regulatory provisions** on blood and blood products (Italy has transposed and fully applies all the pertinent EU directives).
- **Appropriate management and clinical utilisation** of blood resources [including PDMPs and *patient blood management* (PBM) programmes)].
- Continuous **development of transfusion medicine**, aligned with scientific progress.
- Blood system's accountability, effectiveness and sustainability.

THE ITALIAN BLOOD SYSTEM, Pursuant to Law of 21 October 2005

“New discipline for blood transfusion activities and national production of plasma-derived medicinal products”

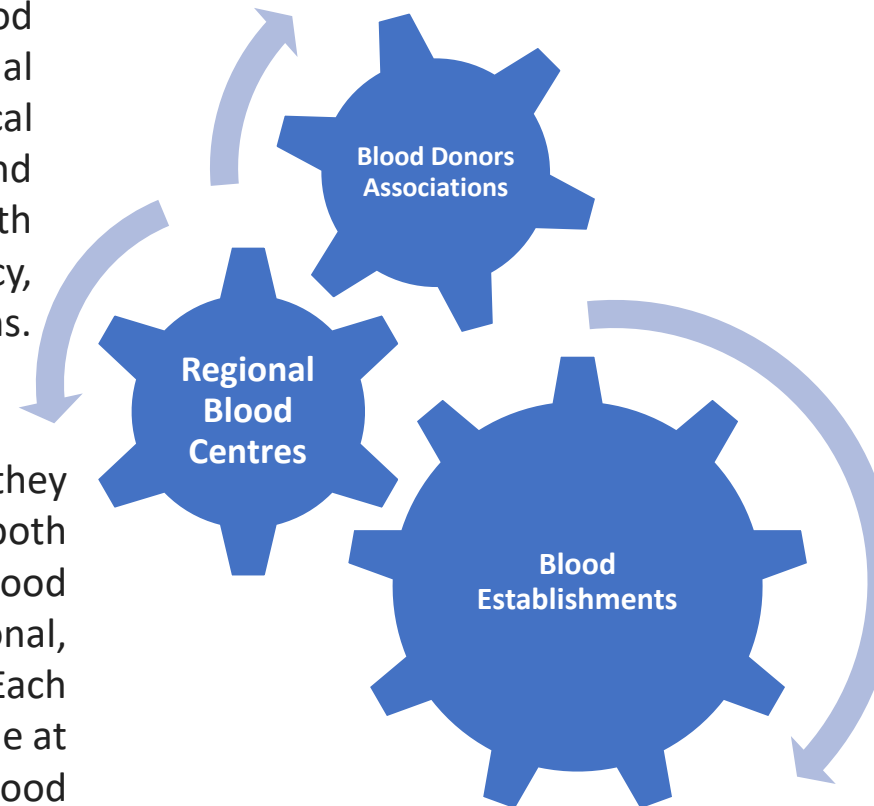
Overview of the Italian national blood system

Regional Blood Centres:

in each of the 21 regions, a Regional Blood Centre is established by law. The regional Blood Centres coordinate the related local networks of Blood Establishments and Blood Collection Units, complying with national regulation and self-sufficiency, quality and safety plans.

Regional Health Authorities:

they inspect, authorize and accredit both Blood Establishments and Blood Collection Units, according to regional, national and European legislation. Each regional inspection team must include at least one nationally qualified blood inspector from the CNS register.

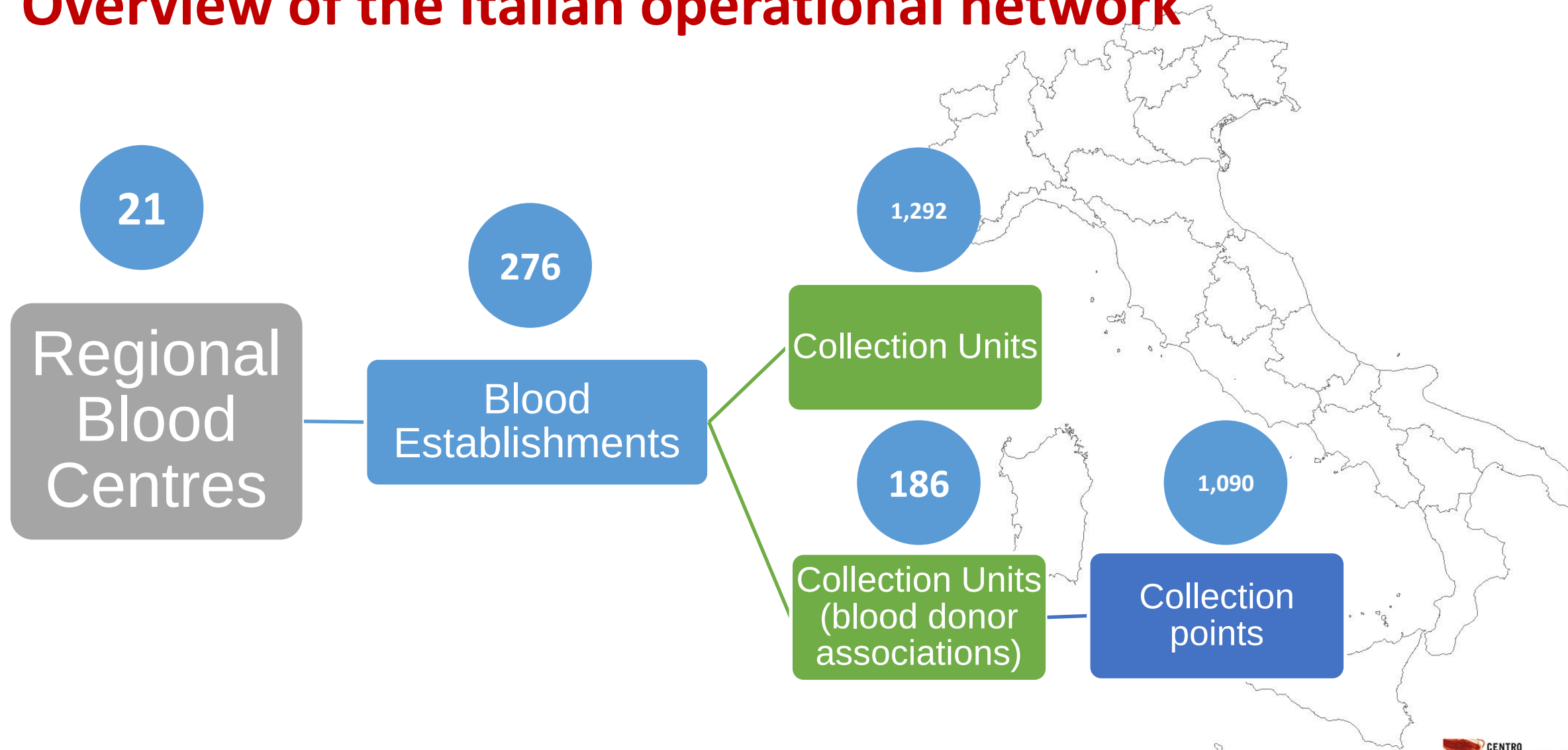


Blood Establishments: in addition to blood and blood component collection, processing, testing, storage and distribution, most Blood Establishments also work as hospital blood banks and Transfusion medicine departments.

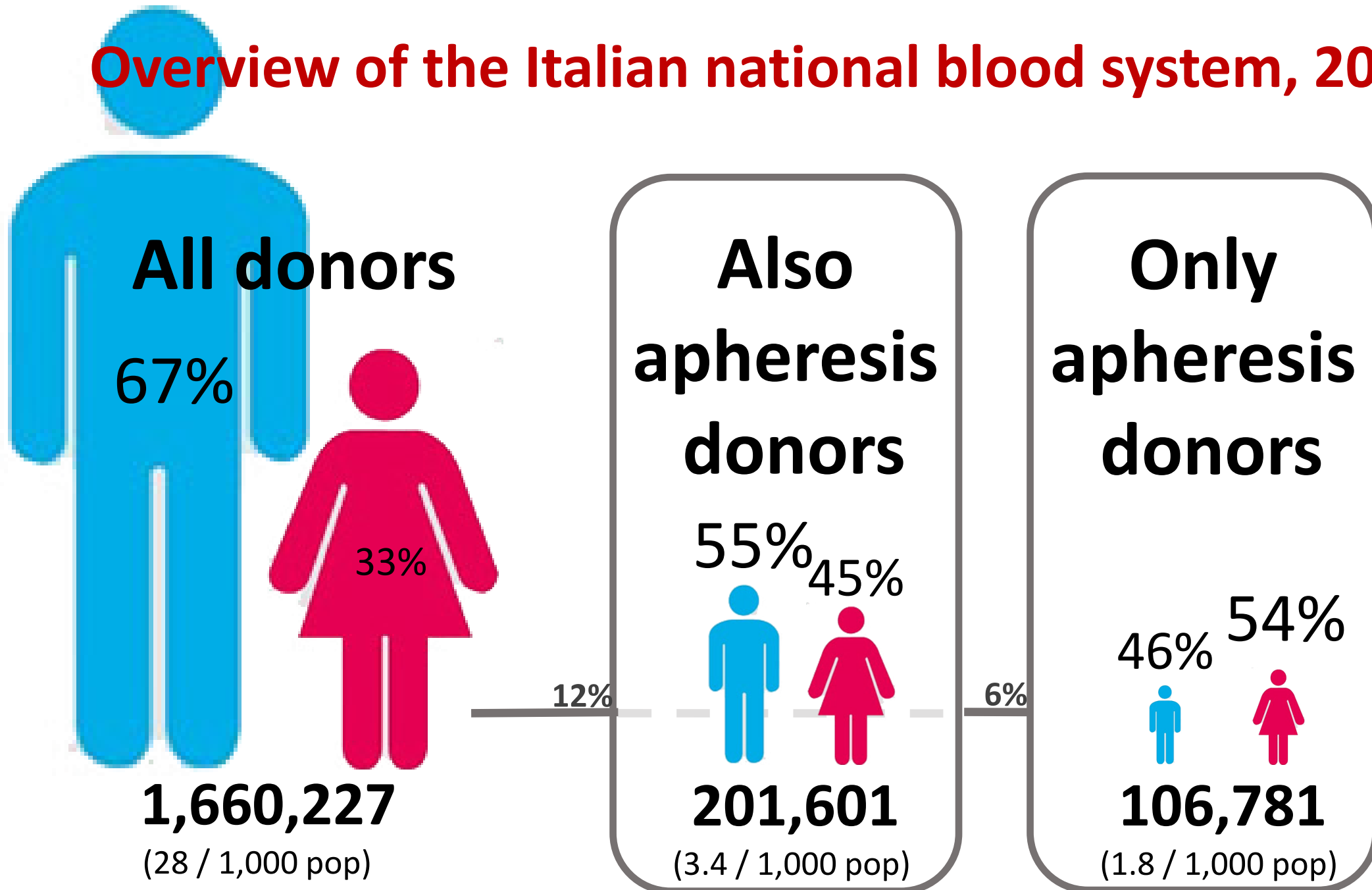
Blood Donors Associations:

four main blood donors organisations (AVIS, FIDAS, FRATRES, CRI) that are highly involved in the blood donor management. By law, they can run Blood Collection Units upon the release of specific regional authorisation and accreditation, under the technical control of both Blood Establishments and Regional Blood Centres.

Overview of the Italian operational network



Overview of the Italian national blood system, 2022



Overview of the Italian national blood system, 2022

2,981,019
Donations

51 / 1,000 pop

2,555,886
WB

86% of total donations
43 / 1,000 pop

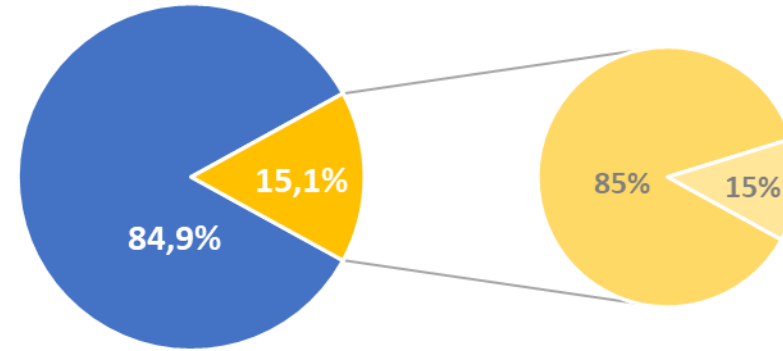
424,855
Apheresis

14% of total donations
7 / 1,000 pop

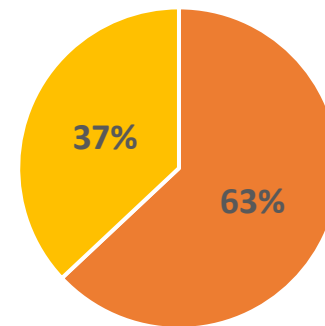
362,694
Mono

6 / 1,000 pop

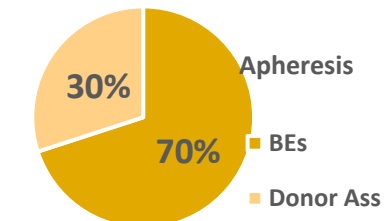
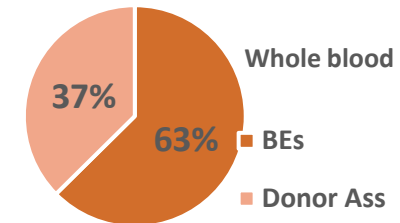
62,161
Multi



■ Whole blood ■ Apheresis ■ Plasmapheresis



■ BEs ■ Donor Ass



Plasma and PDMPs

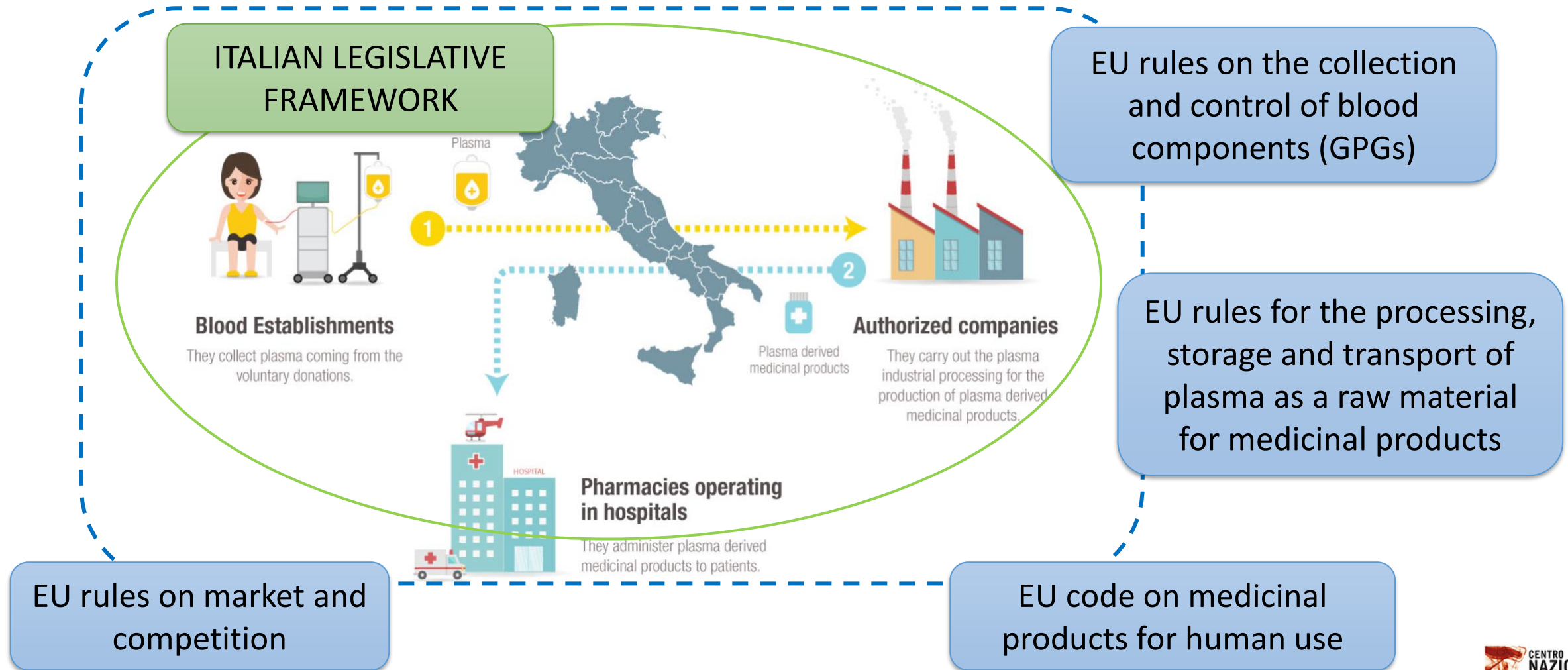
The toll-fractionation system

(the Italian way to PDMPs national provision)

- The plasma collected in Italy comes from voluntary, periodic, responsible, anonymous and non-remunerated donations
- The Regions, individually or in association, send the plasma collected by their BEs to the authorised company to be industrially transformed into PDMPs
- The contract with companies, which operate as service providers, is considered a "toll fractionation process"
- The service provider undertakes to produce the quantity and to guarantee the quality of the PDMPs requested by the Regions
- The Regions have the right to full ownership of the plasma sent for industrial processing, of all the pharmaceutical specialties derived from it, as well as of the residual raw material



Regulatory context of the toll fractionation system



The Italian Blood System and PDMPs

Law no. 219 October 21, 2005

Founding Principles

Art. 1
National Self-sufficiency

Art. 2
VNRB donation
PDMPs production is
part of Transfusion
medicine activities

Art. 5
Transfusion medicine
activities (including
the PDMPs
production) are
BHCLs

Art. 15 (PDMPs production)

4 Ministerial
Decrees
April 12, 2012

Ministerial
Decree
December 5,
2014

Ministerial
Decree
December 5, 19
2022

Art. 16 (import- export)

State-Regions
Agreement
February 7,
2013

Ministerial
Decree
December 2,
2016

Instruments

State-Regions
Agreements
October 20,
2015
June 17, 2021

State-Regions
Agreement
February 7, 2013

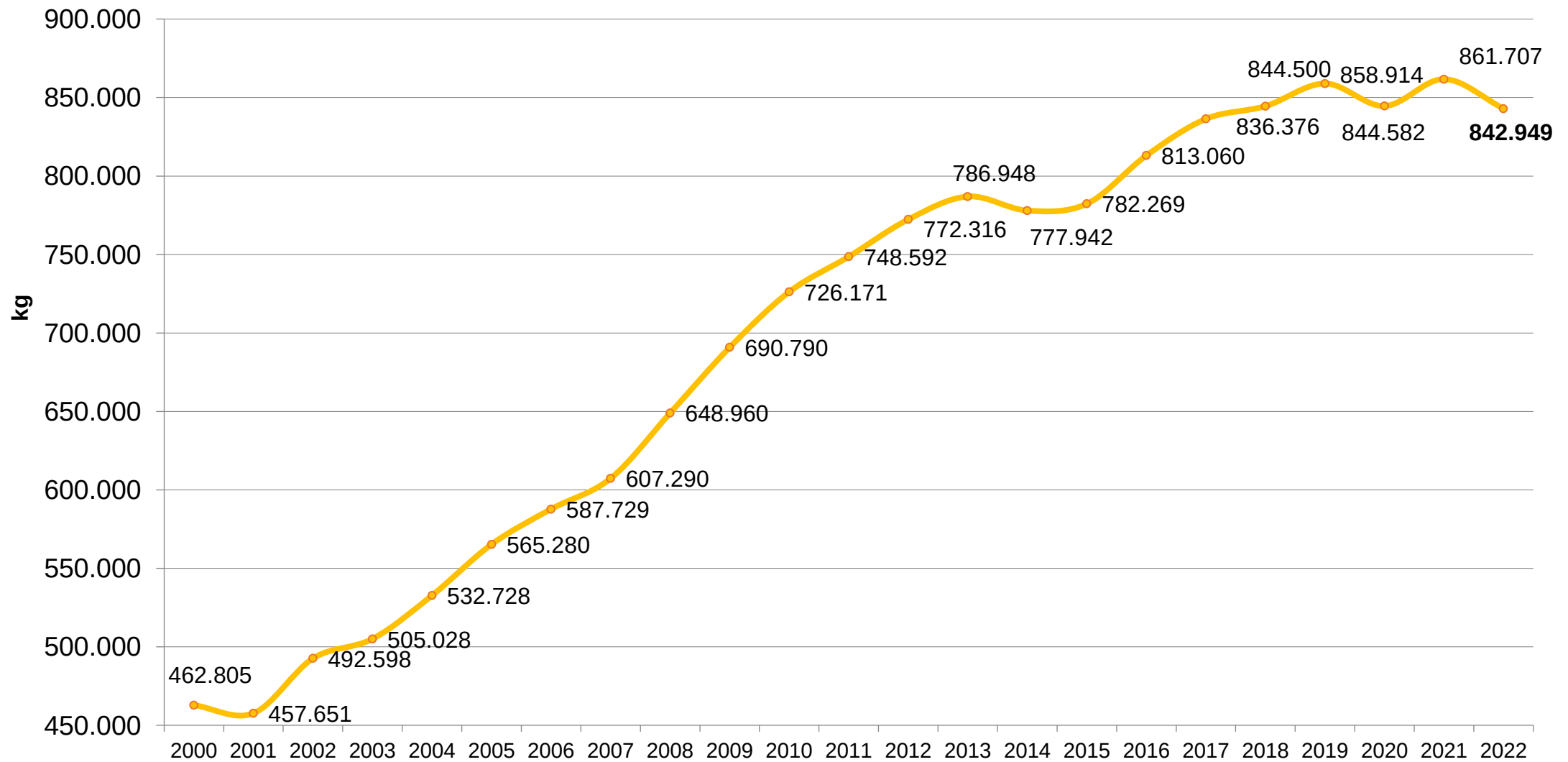
Lgs.D
261/2007

Art. 26

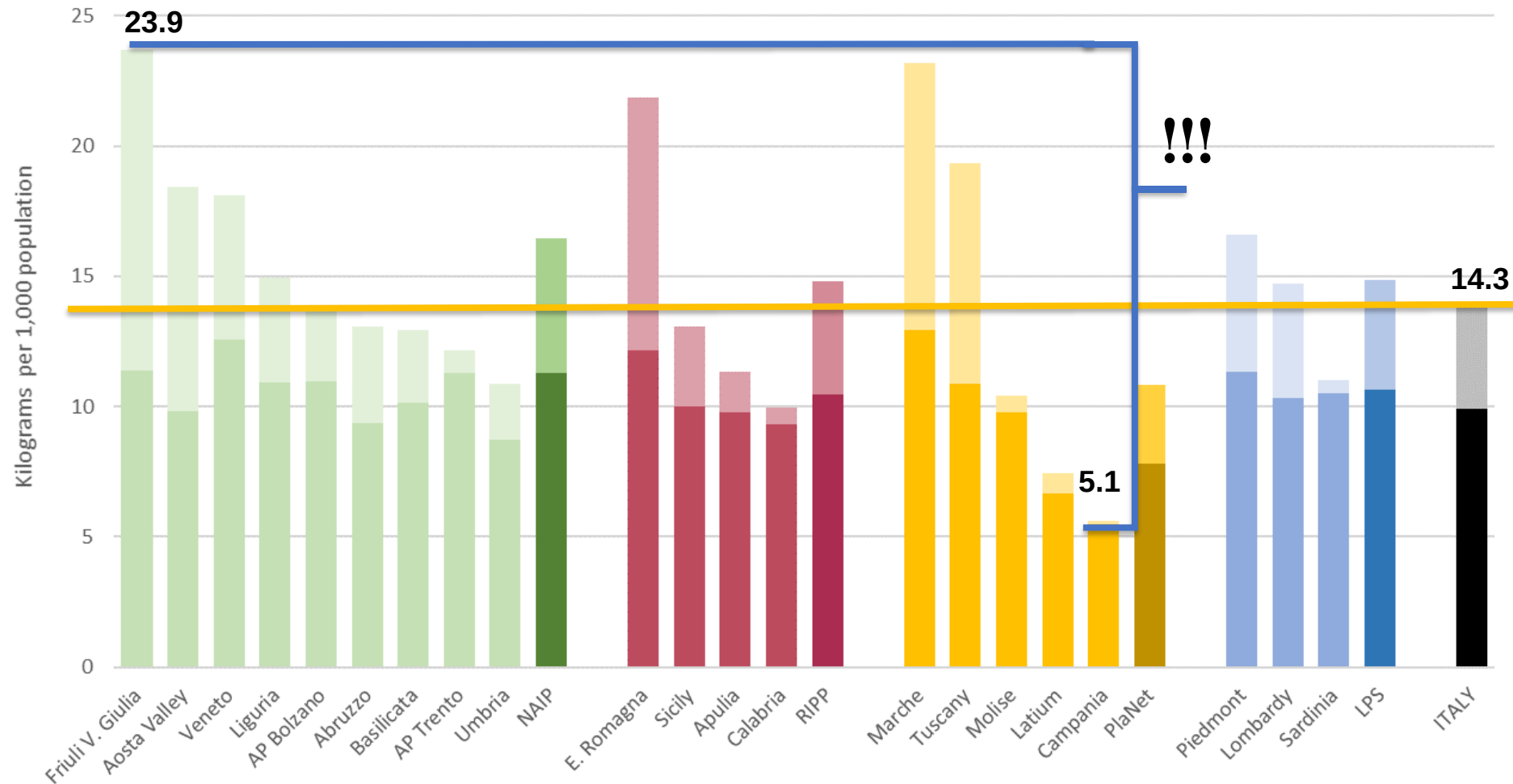
Ministerial
Decree
December 2, 2016

**Plasma and
PDMPs National
Plan
2017 - 2021**

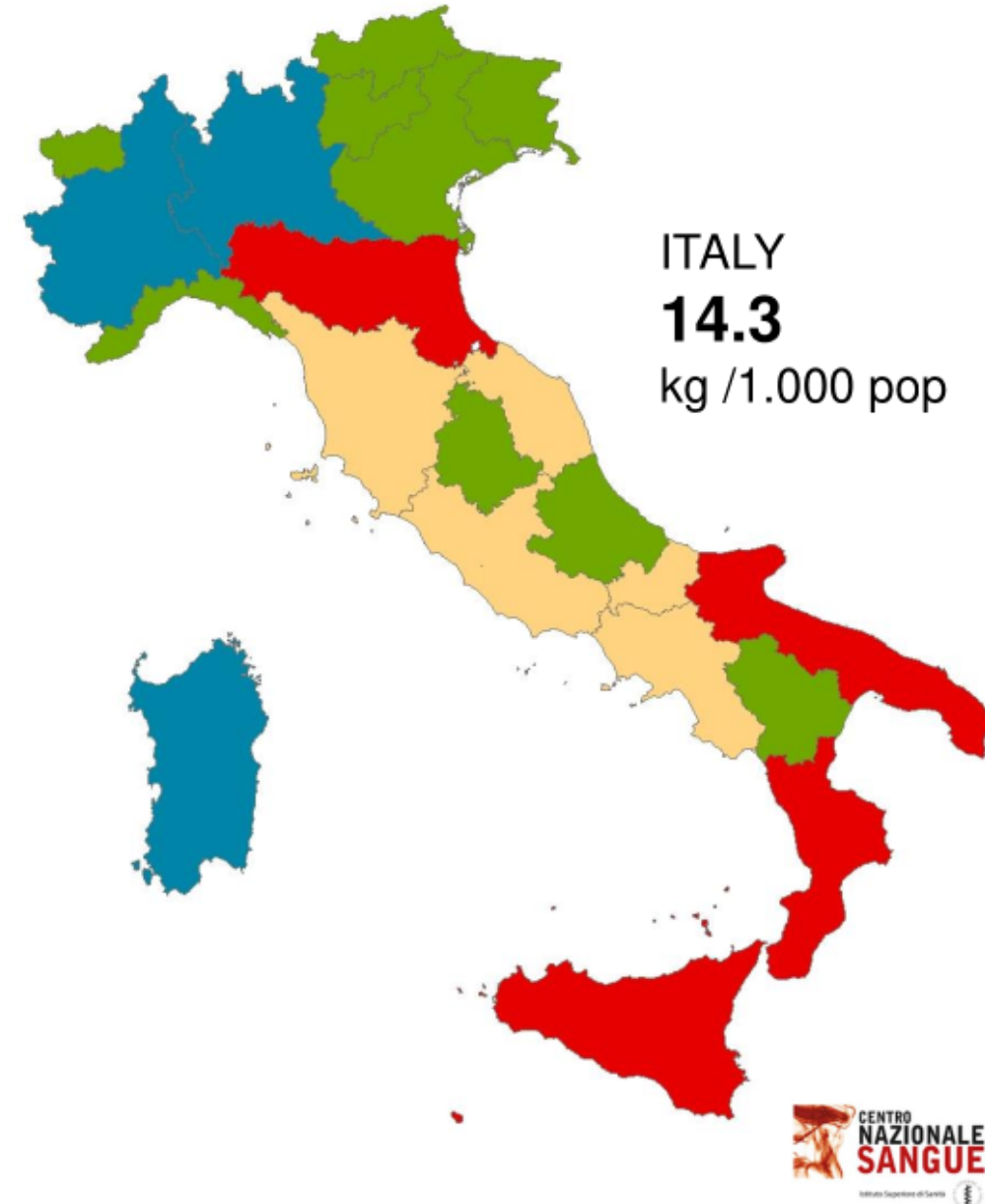
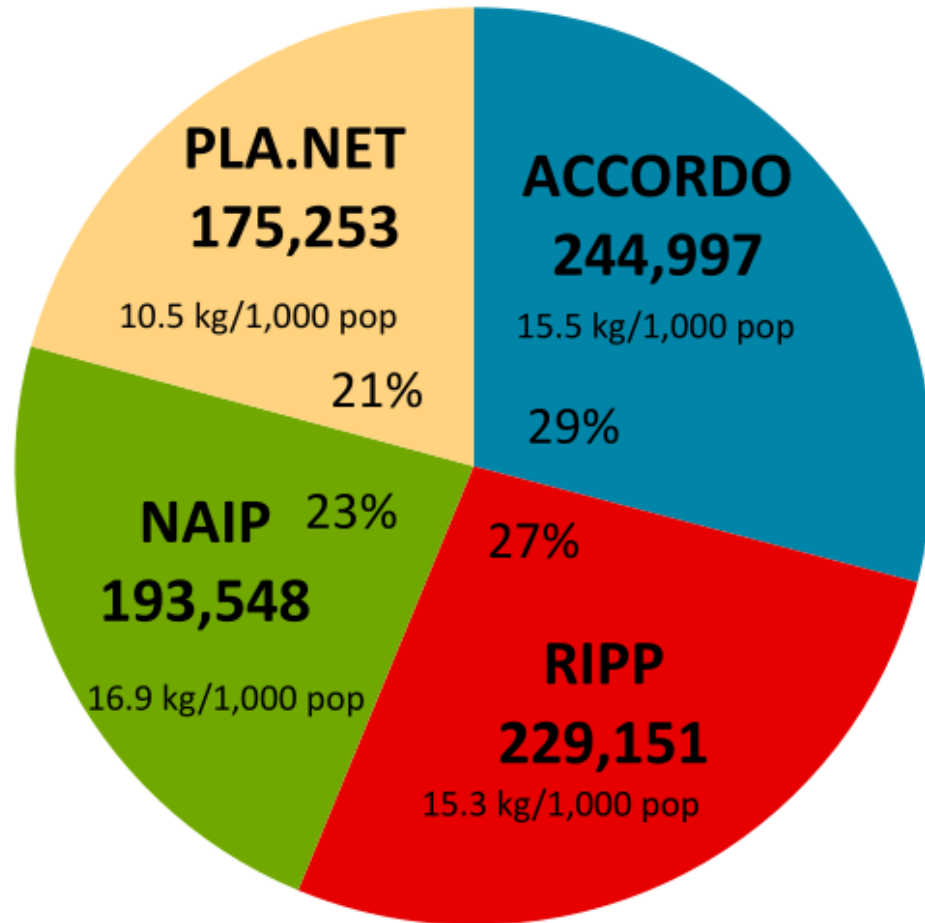
Plasma for fractionation (kg) 2010-2022



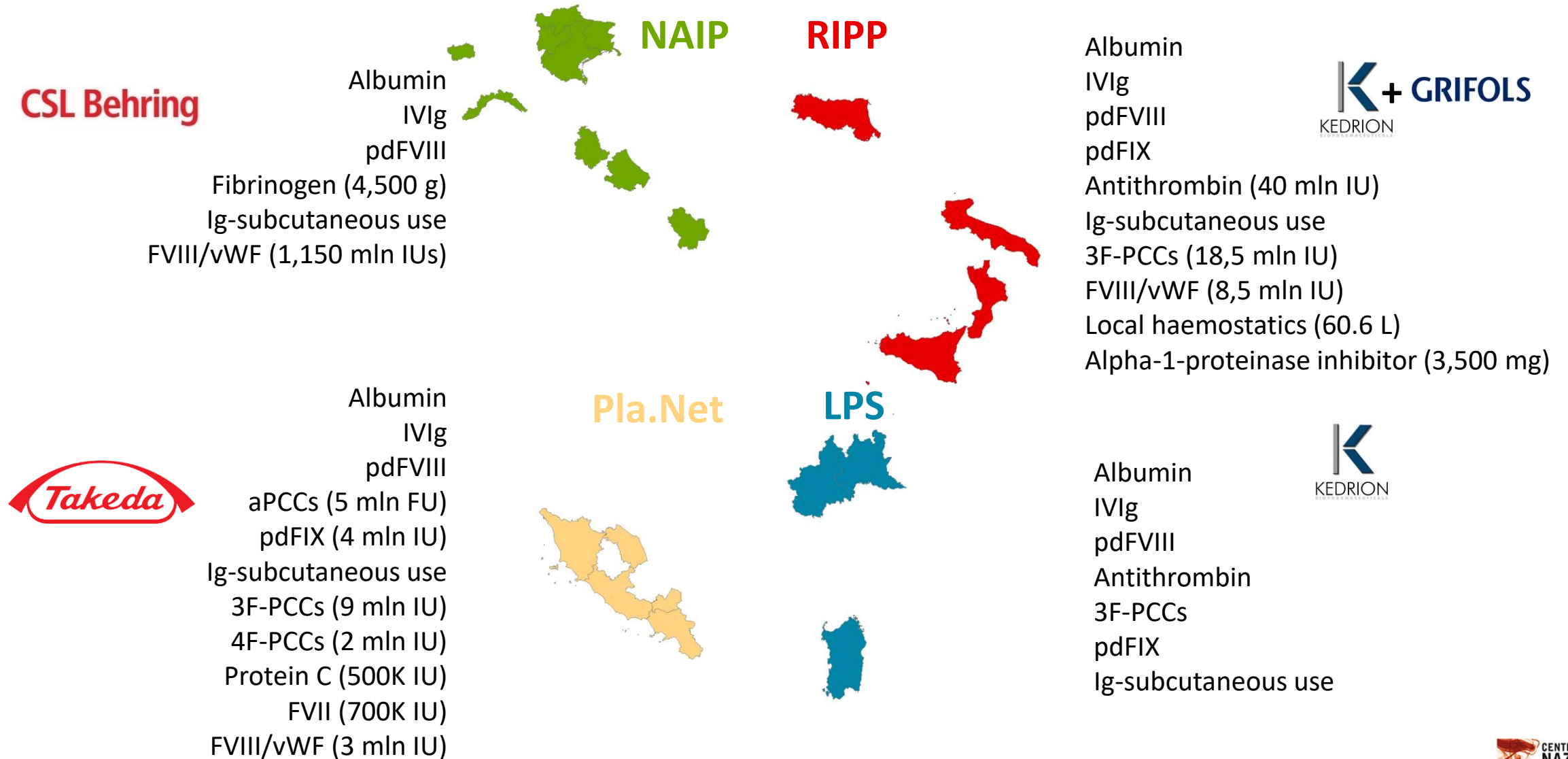
Interregional agreements: scenario in 2015 - 2022



Interregional agreements: scenario in 2015 - 2022



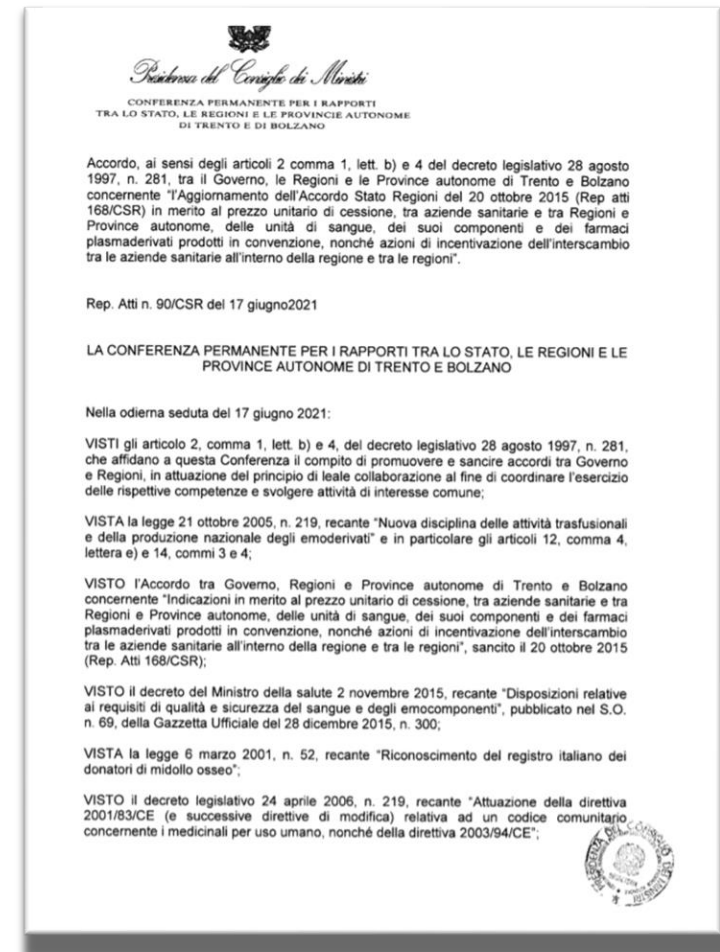
Interregional agreements: Italian scenario in 2022



State-Regions Agreement June 17, 2021

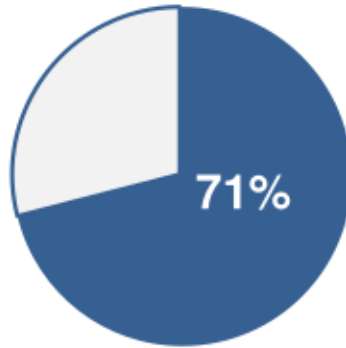
Products exchange tariffs

	State-Regions Agreement 2015	Unit Market price 2021	State-Regions Agreement 2021
	Euro/gr/IU	Euro/gr/IU	Euro/gr/IU
Albumin (g)	1.90	2.67	1.56
IVIg (g)	35.00	46.62	30.02
SCIg (g)		53.2	40.40
FVIII/von Willebrand Factor (IU)		0.50	0.40
FIX (IU)	0.23	0.46	0.38
3F-PCCs (IU)	0.24	0.27	0.19
Antithrombin (IU)	0.225	0.11	0.09
FVIII (IU)	0.23	0.42	0.33
4F-PCCs (IU)		0.29	0.24
Fibrinogen (g)		434.6	341.26

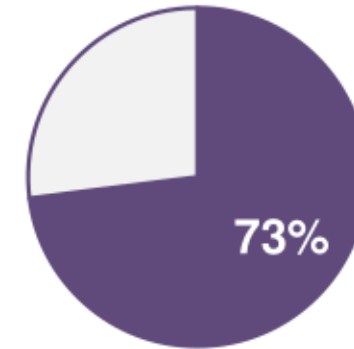


Self sufficiency - Italy - Year 2021

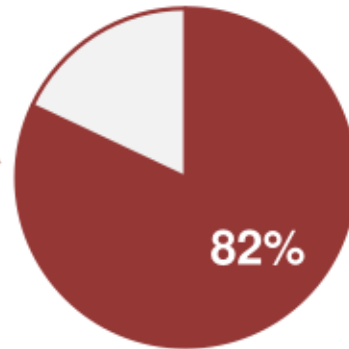
ALBUMIN



ANTITHROMBIN



IV IMMUNOGLOBULIN**

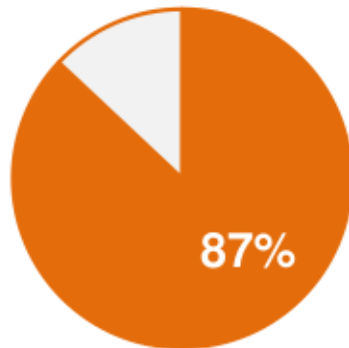


SC IMMUNOGLOBULIN

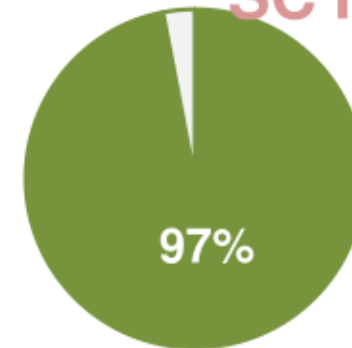


FIX+CCP3

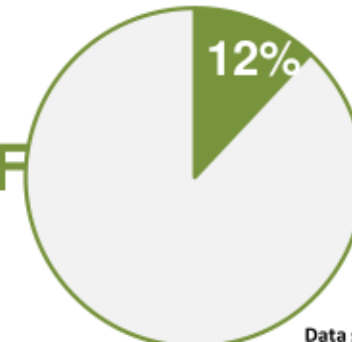
(only CCP3 self -
sufficiency=91%
Only FIX self-
sufficiency=63%)



FVIII*



FVIII/vWF



FIBRINOGEN°



*100% of total demand for contract-manufactured products

** The value not includes Pentaglobin™

° on the total demand for contract-manufactured products

Haemovigilance network

Italian haemovigilance network

Haemovigilance systems are regulated by specific national laws and by European Directives, transposed into national laws which state the procedures that must be adopted for the reporting of adverse reactions in recipients during or after transfusion, related to the quality and safety of transfused blood components, including the reporting of every case of transfusion transmitted infection.

- Required by law 219/2005
- Regulated by decree 261/2007 (Directive 2002/98/CE)
- Regulated by decree 207/2007 (Directive 2005/61/CE)

Italian haemovigilance network

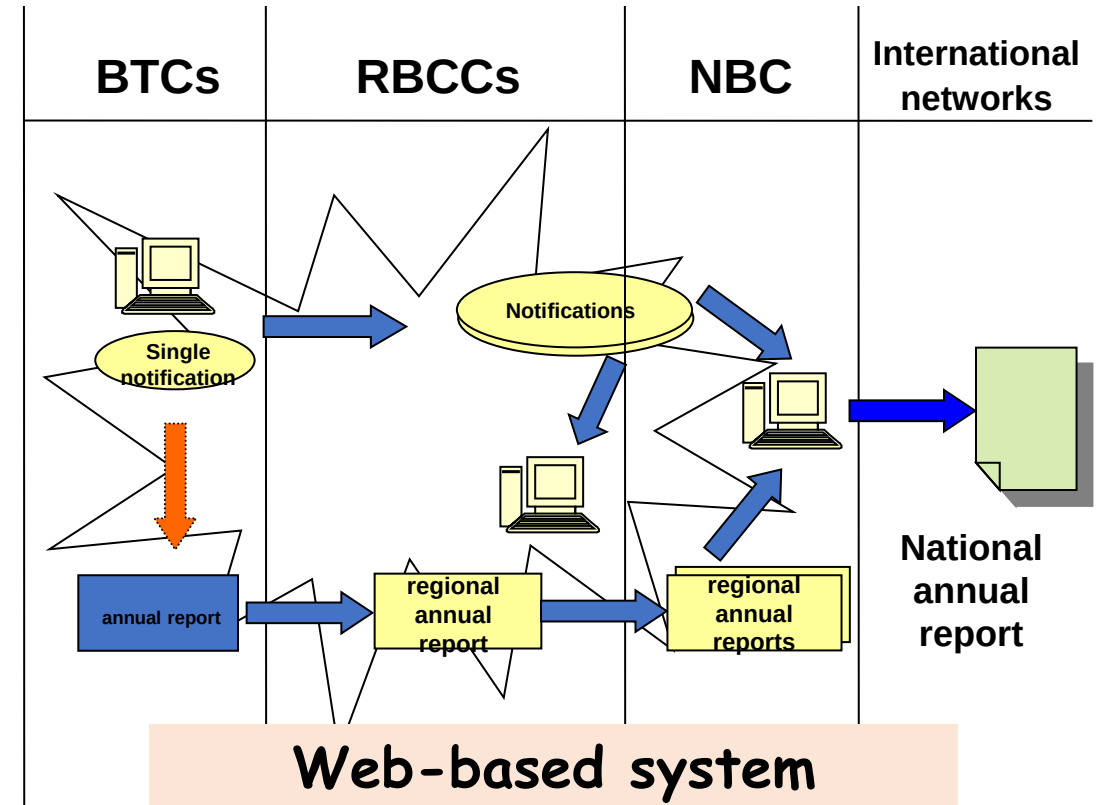
The Italian National Blood Centre is in charge of the coordination of the National Blood Information System (Sistema Informativo dei Servizi TRAsfusionali, SISTRA), which was established by ad hoc Ministerial Decree within the Ministry of Health's New Health Information System (NSIS).



The aim of SISTRA is to promote the standardisation and comparability of data at national level through the simplification of their aggregation and processing to produce national reports.

In Italy

- ❖ Blood Establishments are responsible for the collection of haemovigilance data
- ❖ Blood Establishments register and report adverse events occurring in their organisation and must collect data from the related clinical facilities and Blood Collection Sites
- ❖ Regional Blood Coordination Centres are responsible for communicating to the National Competent Authority annual reports concerning adverse reactions in recipients and in donors and adverse events occurred in related BEs.
- ❖ The same flow of information is in place also for the epidemiological surveillance of donors.

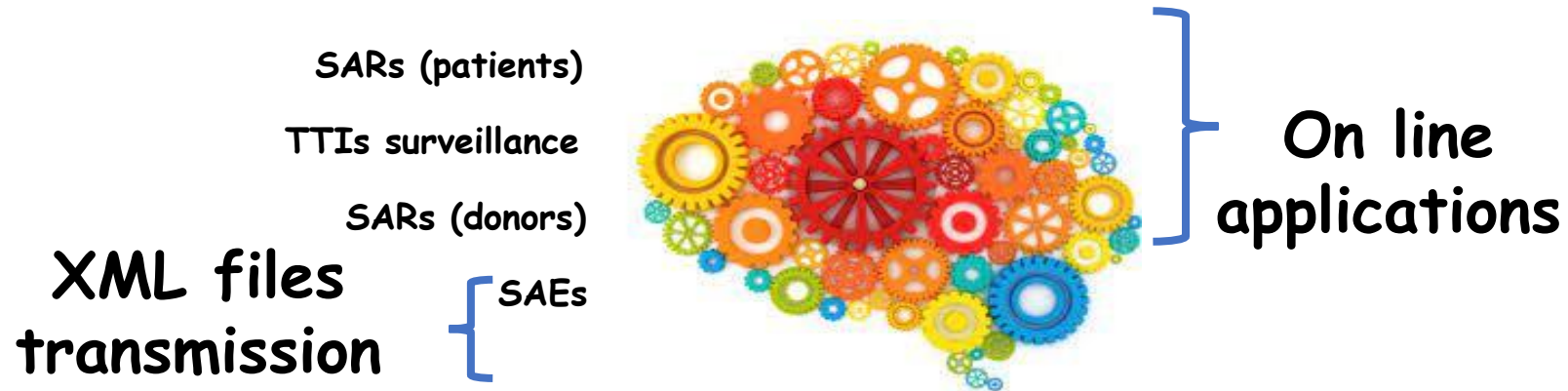


In each organisation (BEs, RBCCs and the CNS) there is a person responsible for haemovigilance.

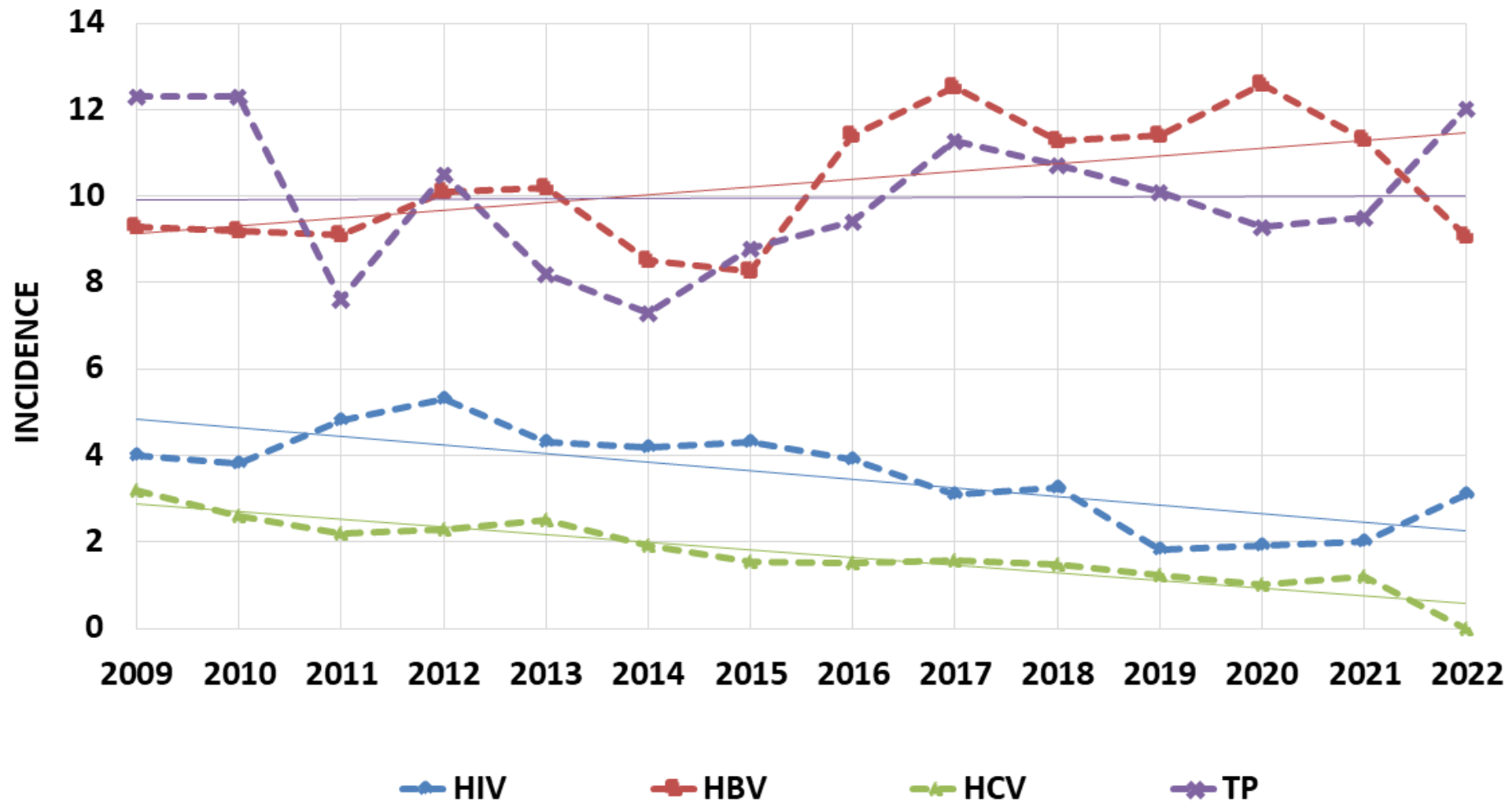
The specific section of SISTRA dedicated to the haemovigilance includes

- adverse reactions in recipients
- adverse reactions in donors
- adverse events
- epidemiological surveillance of donors

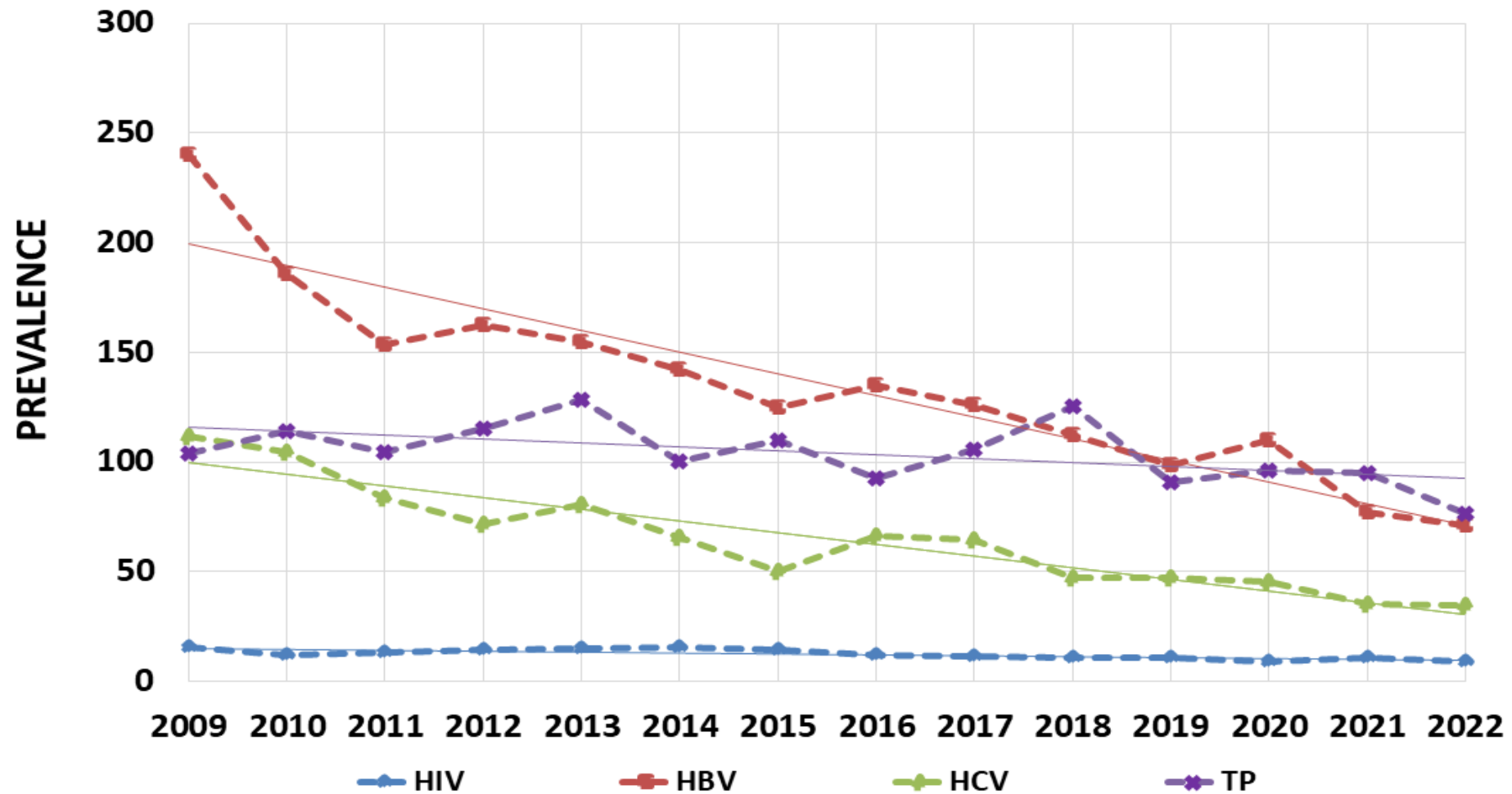
Data Transmission



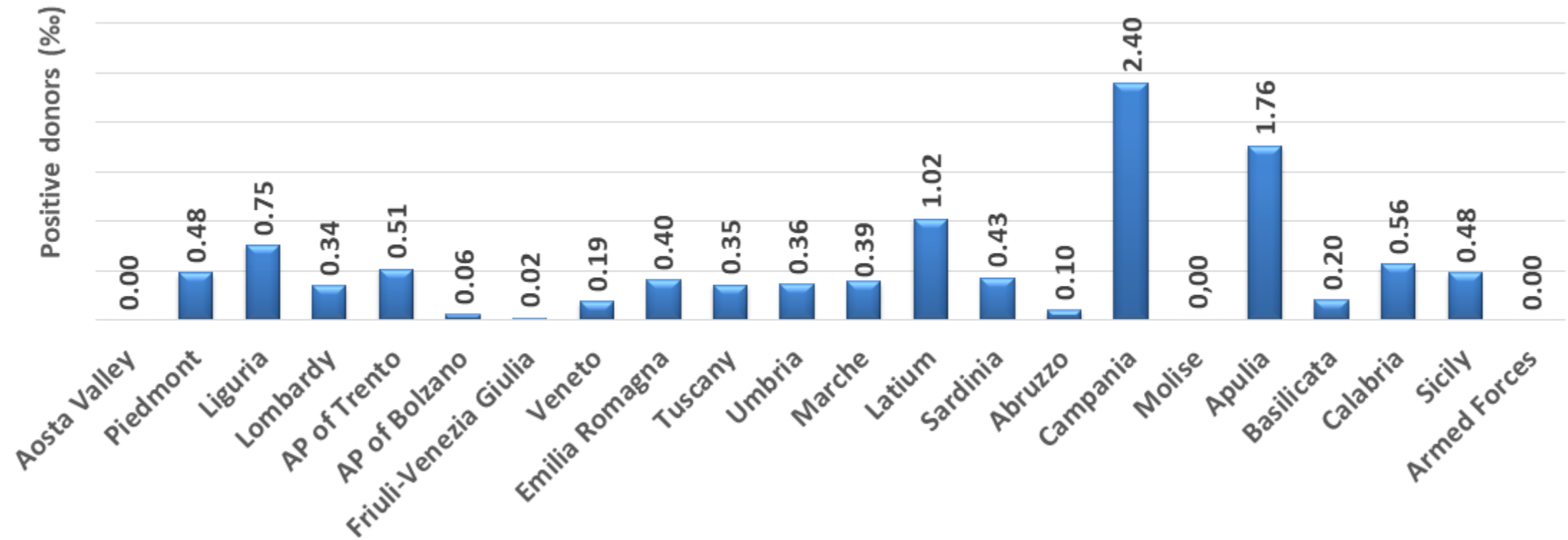
Epidemiological surveillance of blood donors



Epidemiological surveillance of blood donors

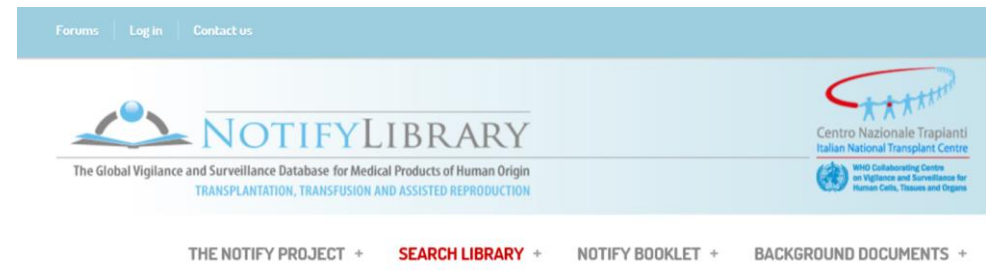
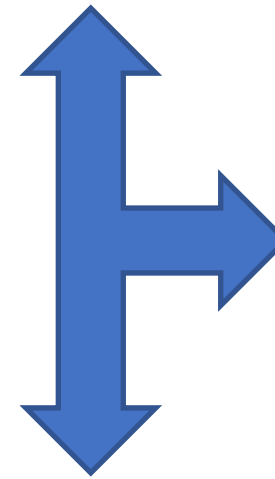


Positive donors for all viral markers





Serious Adverse Reaction(s) and Event(s) Directive 2005/61/EC



(self-advertising)
Explicit contents!



<https://www.centronazionalesangue.it/rapporti-tecnici/>

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attention!*

