



Romania experience with the EDQM B-PTS & B-QM Programmes

Keeping up with Reality and Quality: A challenge for European Blood Establishments

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ROMANIAN BLOOD SYSTEM: A NATIONALLY COORDINATED SYSTEM

ROLE/RESPONSIBILITY

- REGULATING,
- DESIGNATION,
- ORGANISATION & HUMAN RESOURCE
- AUTHORIZATION
- FINANCING

COMPETENT AUTHORITY
MINISTRY of HEALTH

ROLE/RESPONSIBILITY

- INSPECTION
- CONTROL
- HAEMOVIGILANCE

Departments

State Sanitary Inspection (SSI)

COUNTY PH
Authority
Authorisation

COUNTY authority
Inspection &
control

DONORS

BLOOD SUPPLY

HOSPITALS

PATIENTS

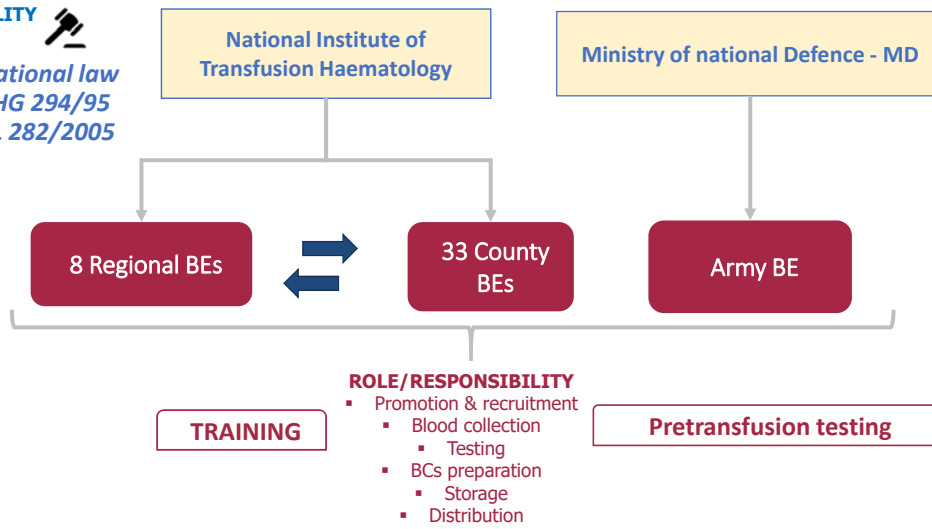
BLOOD SUPPLY IN ROMANIA

ROLE/RESPONSIBILITY

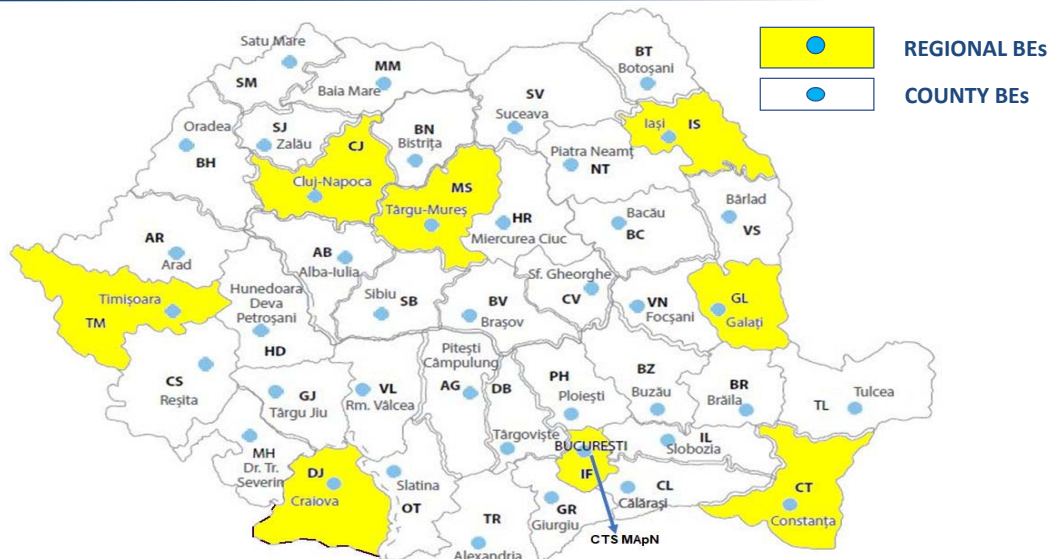
- Management
- Organization
- Coordination
- Monitoring
- Research
- Training



National law
- HG 294/95
- L 282/2005



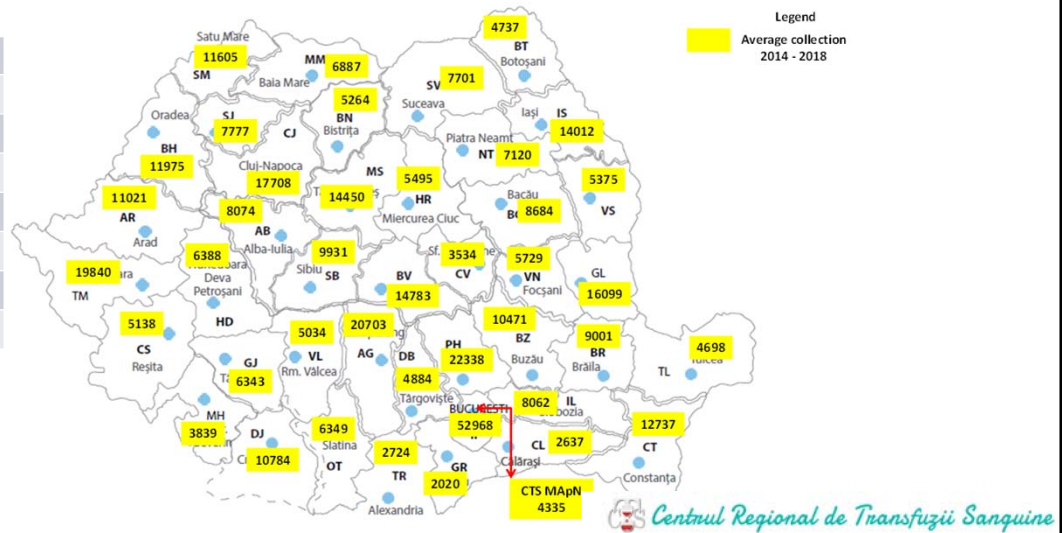
BLOOD ESTABLISHMENTS



AVERAGE COLLECTION (WHOLE BLOOD & APHERESIS) 2014-2018

YEAR COLLECTION

YEAR	COLLECTION
2012	399848
2013	428140
2014	429542
2015	420072
2016	407560
2017	412837
2018	418185
2019	426566



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B-PTS PROGRAMME – OUR NEEDS

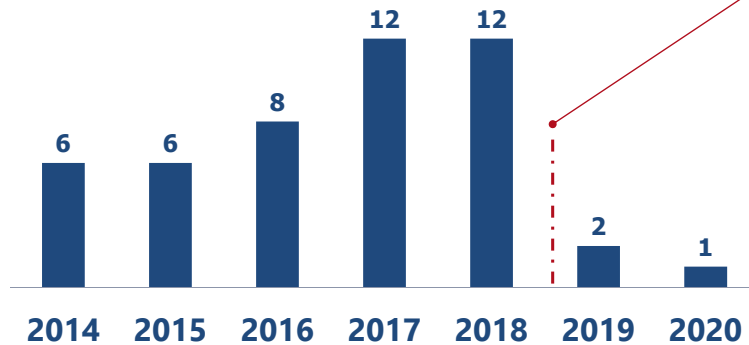
- **Quality Control: required as per Ministerial Order 1132/2006** transposing Directive 2005/62/EC, including:
 - Internal quality control
 - External quality control i.e. Proficiency testing Scheme for Transfusion Transmitted Infections → *PTS provider: BIODEV*
- **Issue: 2006-2013 – PTS programme not available at national level for immuno-haematological testing – Why??**
 - Limited resources
 - Barrier to register the existing commercial PTS-IH in Europe considering high costs
- **2013: Opportunity for Romanian BEs – EDQM B-PTS Programme – IH scheme & grouped shipments:**
 - **Opportunity for 6-12 BEs/ country** to access to the B-PTS IH , given grouped shipment for samples, paying ONLY one moderate fee for transport!

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B-PTS PROGRAMME – OUR EXPERIENCE

Romanian BEs Participation in EDQM IH-B-PTS



Cancellation of group Shipments leading to increased costs!

PTS-IH scheme available from commercial suppliers at national level → facilitate purchasing procedure

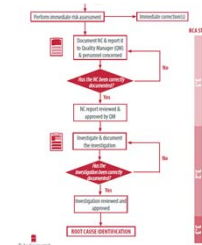
B-PTS PROGRAMME – OUR EXPERIENCE

The **most beneficial aspects** for participating BEs & Romania:

- Ensured **compliance** with EU legislation, GPGs and national legal requirements
- Opportunity to assess BEs **performance** and equipment/methods used and compare with other peers BEs in Europe → increased performance of our BEs labs → *SARE report: reactions in patient related to immunoincompatibility still an issue!*
- Better understanding** of PTS scope & objectives
- Confidentiality** – coding of participating BEs
- Objective & clear** assessment of results
- Comprehensive and informative **report**
- Increase of **self-confidence** of medical staff involved on their daily work

Additional value: Education programme, goes beyond the objective of providing external quality assessment samples

→ **Guidance for root-cause analysis**



I would recommend the B-PTS programme because:

- Accessible
- Professionally organised and managed
- User - friendly used
- Excellent organization of the exercise
- Samples originating from blood donors
- Broad range of tests, covering both donors and patients related testing algorithms
- Make BEs member of the European transfusion community

→ Opportunity to compare our performance and quality of testing with Peers BEs from almost all European country, member/observers to the Council of Europe

→ Opportunity to identify issues related to reagents, equipments ,methods and take measures