EU RAPID ALERT PLATFORM

Multi-Country Workshop on Increasing Blood Availability and Providing the Highest Donor and Patient Safety in Transfusion Therapy in Emergency Special Circumstances _7-9 July 2014

Dr Imad SANDID
French National Agency for Medicines and Health Products Safety (ANSM)
Biological Products Department
Blood Components Team

QUICK ALERTS

Why quick alerts?

- Article 9 of Directive 2005/61/EC: *"Member States shall ensure that their competent authorities communicate to each other such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded.*
- Annex II Dir 2004/33/EC: Communicable diseases
  - Annex 2.3 Dir 2004/33/EC: Notification of deferrals to the Commission *« with a view to Community action »*
- Scope of the quick alerts:
  - Product defects
  - Threats to health/blood donations
- Approach developed for tissues and cells too

QUICK ALERTS BLOOD

Ex. of quick alerts

- *Chikungunya*
- *West Nile Virus*
- *Dengue*
- *Q fever*
- *Trima Accel Automated Blood Collection System*
- *Ortho Biovue System Cassettes*
- *Macopharma Blood Bags*
- *RadSure (irradiation indicator)*

QUICK ALERTS

Questions to address

- Protocol for triggering/dissemination?
  - Quick alerts vs. Information sharing
  - Information exchange channels
- Preventive measures?
  - In the country directly concerned
  - In the countries potentially threatened
  - Epidemiological/risk assessment
- Follow up?
  - Closure of the alerts
  - Preparation for likely outbreaks

QUICK ALERTS

Development steps

- 2006-2010: Communication by e-mail (mailinglist of representatives of NCAs and MS)
- 2010-2012: CIRCA-CAs and CIRCA-QuickAlerts Blood: sharing all documents in relation of meetings of CAs and other relevant informations, and managing the quick alerts
- Since January 2013: CIRCA-BC (Communication and Information Resource Centre for Administrations, Businesses and Citizens).
- Since February 2014: RAB: Rapid Alerts platform for blood

AGENDA

1. Introduction
2. RAB presentation – Version 1.0
3. RAB data protection
4. RAB Support
5. RAB Standard Operating Procedures
6. Hands-on
7. Next steps

INTRODUCTION (1)

The scope of the Rapid Alert system for human blood and blood components (RAB) is to provide the competent authorities of the European Union (EU) and European Economic Area (EEA) countries and the European Commission with **an effective and secure network tool for the exchange of information on urgent measures, to ensure the safety of human blood and blood components for transfusion**.

This rapid exchange of information allows all the Member States to verify immediately whether they are affected by a problem initially raised and for which a precautionary/corrective measure should be implemented.

The system includes:

- An "administration" module available for restricted list of users within the official list of Competent Authorities (CA) and members of the European Commission (EC) in order to create, follow-up and consult alerts and final reports on tissues and cells.
- An alert form and notification process
- A set of notifications/reminders (based on deadlines and specific events)
- A search functionality
- An easy to use and user friendly interface

INTRODUCTION (2)

Article 9 of the Directive 2005/61/EC regarding communication of information between competent authorities and to the Commission provides for the Member States to

"*ensure that their competent authorities communicate to each other such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded.*"

This procedure does NOT replace the existing national procedures by competent authorities of Member States for communicating the information to the relevant parties in their own national healthcare system.

This procedure is NOT applicable for human or veterinary medicinal products, human tissues and cells, organs or medical devices.

However, where precautionary/corrective actions taken are relevant for these other sectors, an exchange of information should be ensured with the national and European regulatory authorities responsible for these sectors.

RAB PRESNETATION – V1.0

1. Key stakeholders and user roles
2. Registration process
3. Alerts workflow
4. Main system features – Alert and Final Report
5. Notifications/reminders

KEY STAKEHOLDERS

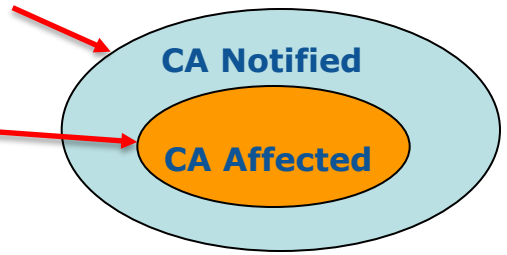
- Main stakeholders
  - **CA** (Competent authorities) *[28 Member States,*
  - *+/- 50* Competent Authorities*]*
  - **EC** (Unit D4 - Substances of human origin and Tobacco control)

- Other stakeholders
  - European Medicine Agency
  - European Centre for Disease Control
  - EWRS contact points
  - EC - other SANCO units:
    - - B2 Medical devices
    - - C3 Health threats
    - - D6 Pharmaceuticals
  - World Health Organisation
  - Other SoHO Network (Tissues & Cells, Organs)

*All the **other stakeholders** will have only a **read access**. Some information like CA initiator person detail,… will not be visible.*

USER ROLES

1. CA (Competent authorities)
    1. CA initiator
        1. Create new alert
        2. Update the alert content
        3. Notify other CA and other stakeholders
        4. Choose the reporter CA (in the list of notified CA) who will write the final report
    2. CA notified
        1. Comments an alert for which it has been notified
        2. Forward the alert to another not yet notified CA
        3. Approve or reject the final report
            - CA 'affected'
                1. Comment the final report
    3. CA reporter (supervisor)
        1. Complete the final report
        2. Submit the final report for comment to all the affected CA
        3. Close the alert



2. EC (European Commission) - Administrator role
    1. Validation of the user access
    2. Management of the reference list / Library
    3. Follow-up of dedicated functional mailbox
    4. Create an alert (as Initiator)

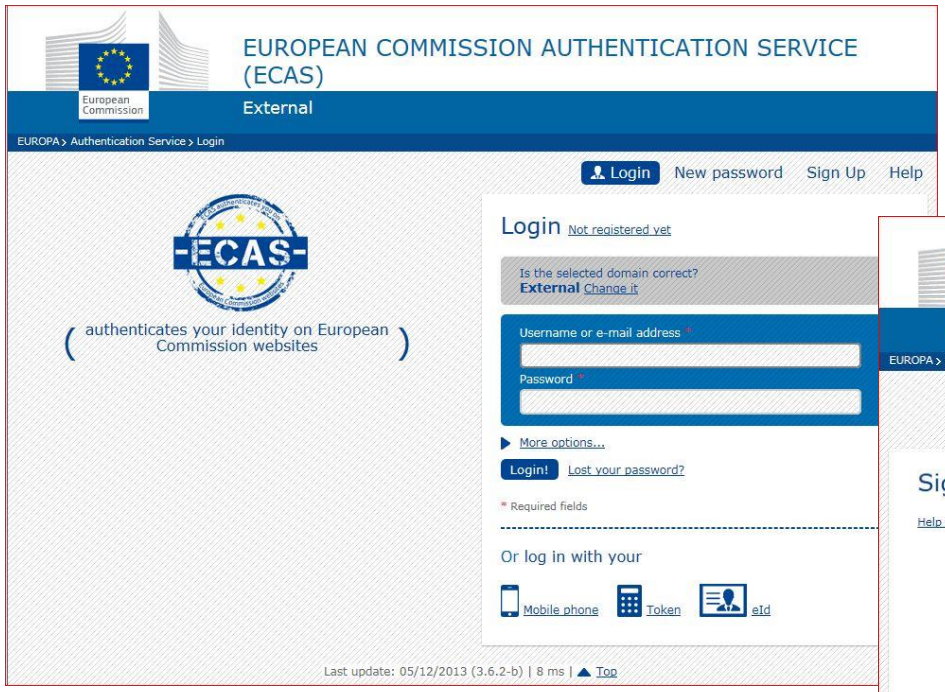
REGISTRATION PROCESS

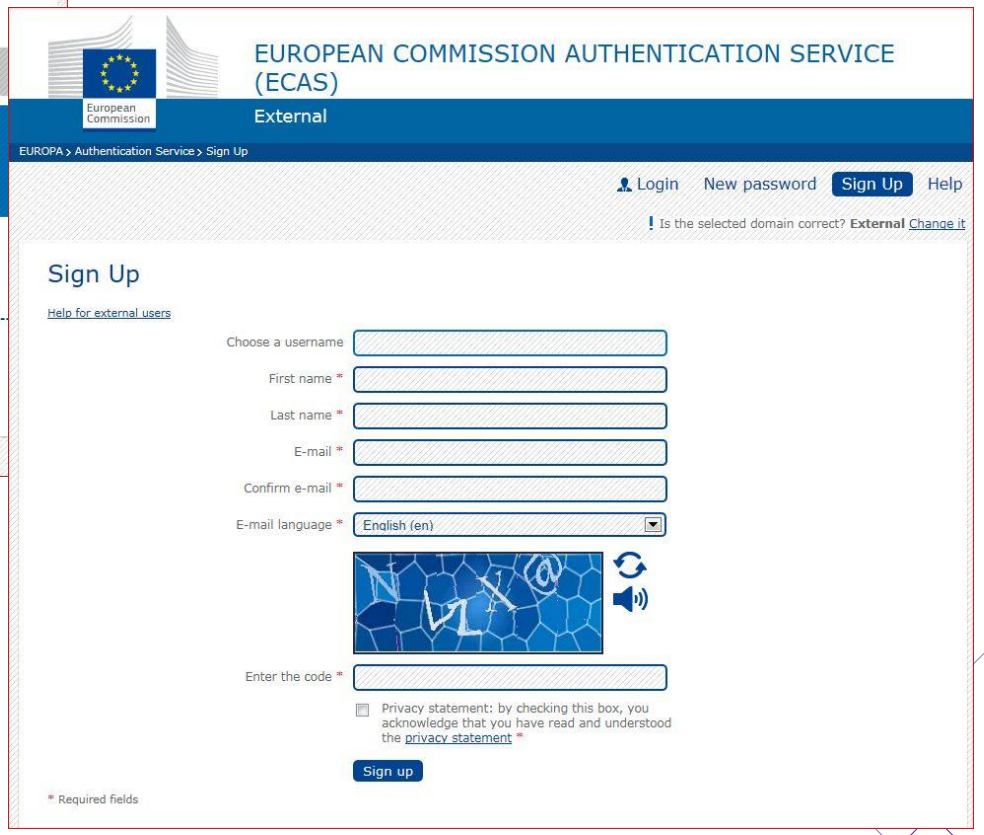
- **Via the official authentication system used by European Commission (ECAS) and getting authorisation via SAAS.**
- **Same login/password**
  1. if member of several networks linked to ECAS
  2. for CIRCA BC
- **Before to access the RAB system the user will have to register via this system.**
- **First validation of the access will be done by EC.**
- **A local administrator can validate accesses for his/her organisation colleagues.**
- **Other stakeholders' access will be managed by the EC-SANCO-SoHO team**

ECAS: CREATE A PERSONAL ACCOUNT (1)

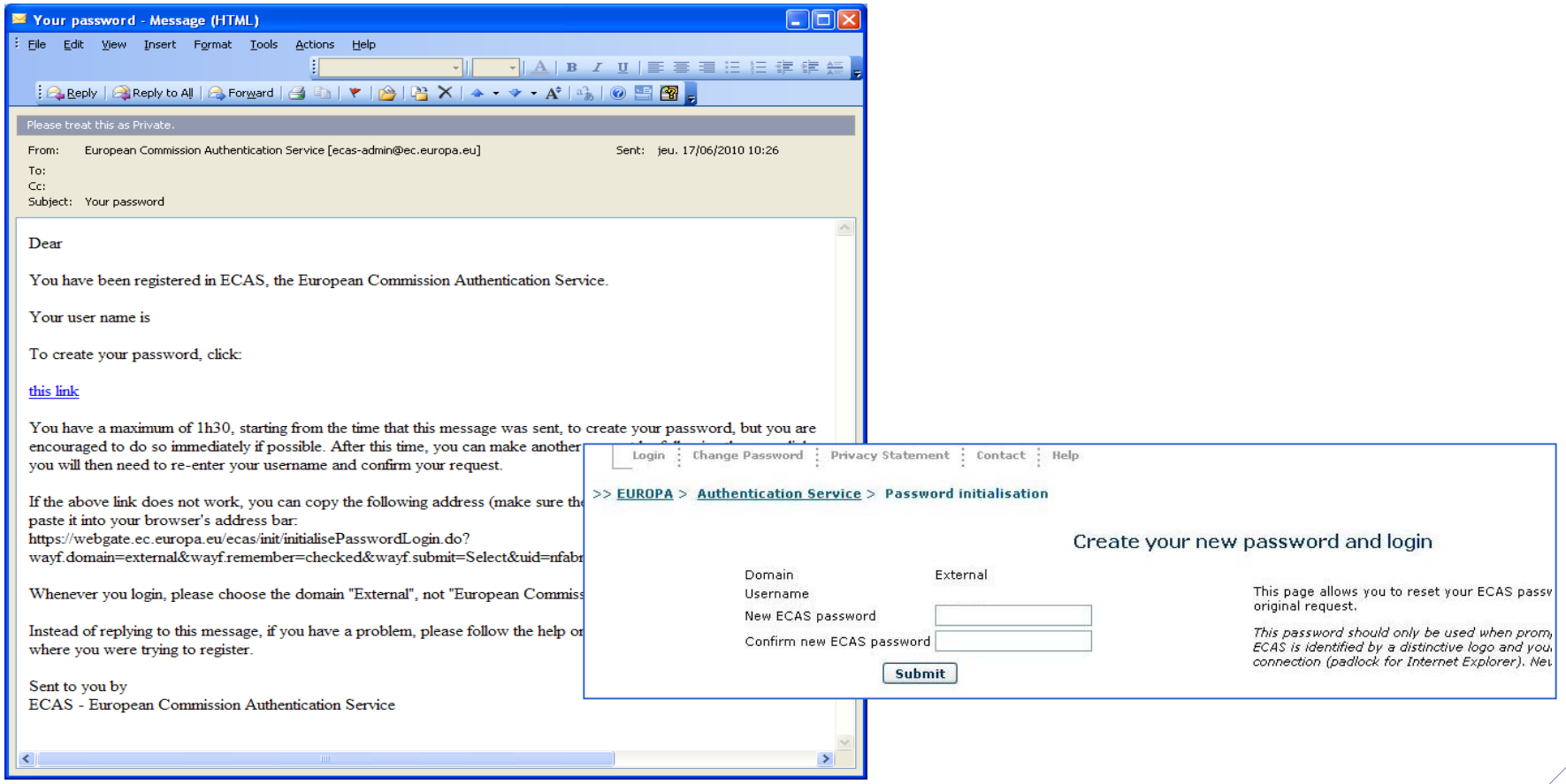
- **ECAS: E**uropean **C**ommission **A**uthentication **S**ervice
- This system provides the user with a login and password to connect to multiple European Commission applications.
- **Remark:** Please do not create generic accounts.
- **URL**: **https://webgate.ec.europa.eu/cas/login**

ECAS: CREATE A PERSONAL ACCOUNT (2)



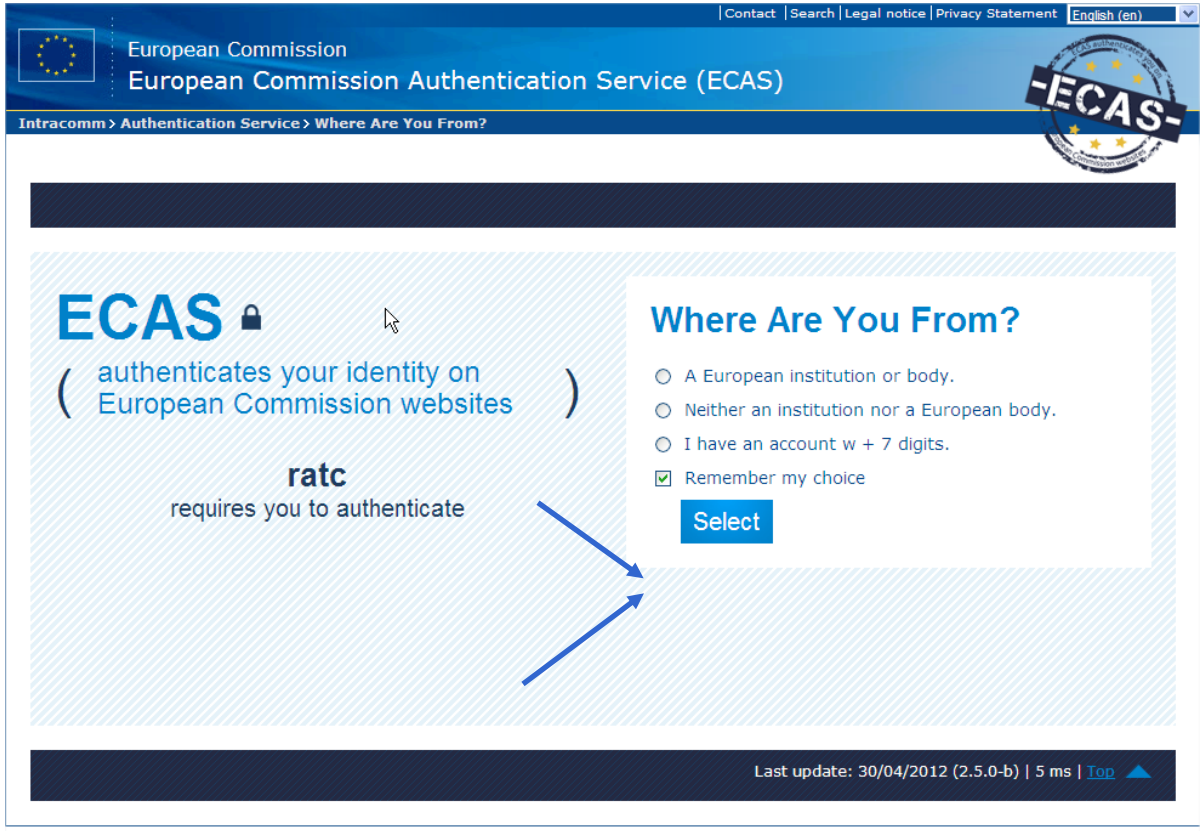


ECAS: CREATE A PERSONAL ACCOUNT (3)

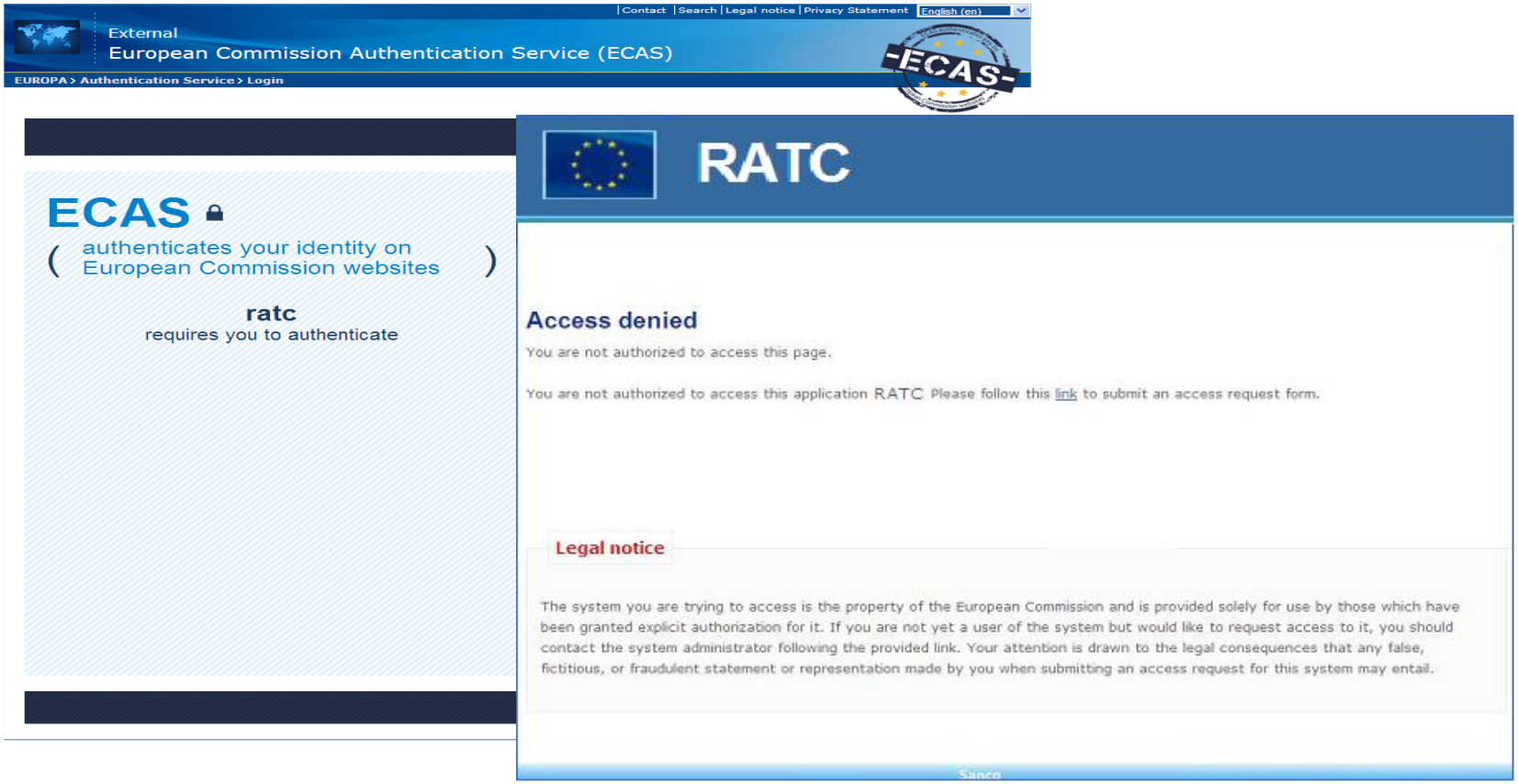


ECAS: FIRST LOGIN (1)

- **URL**: **https://webgate.ec.europa.eu/ratc**



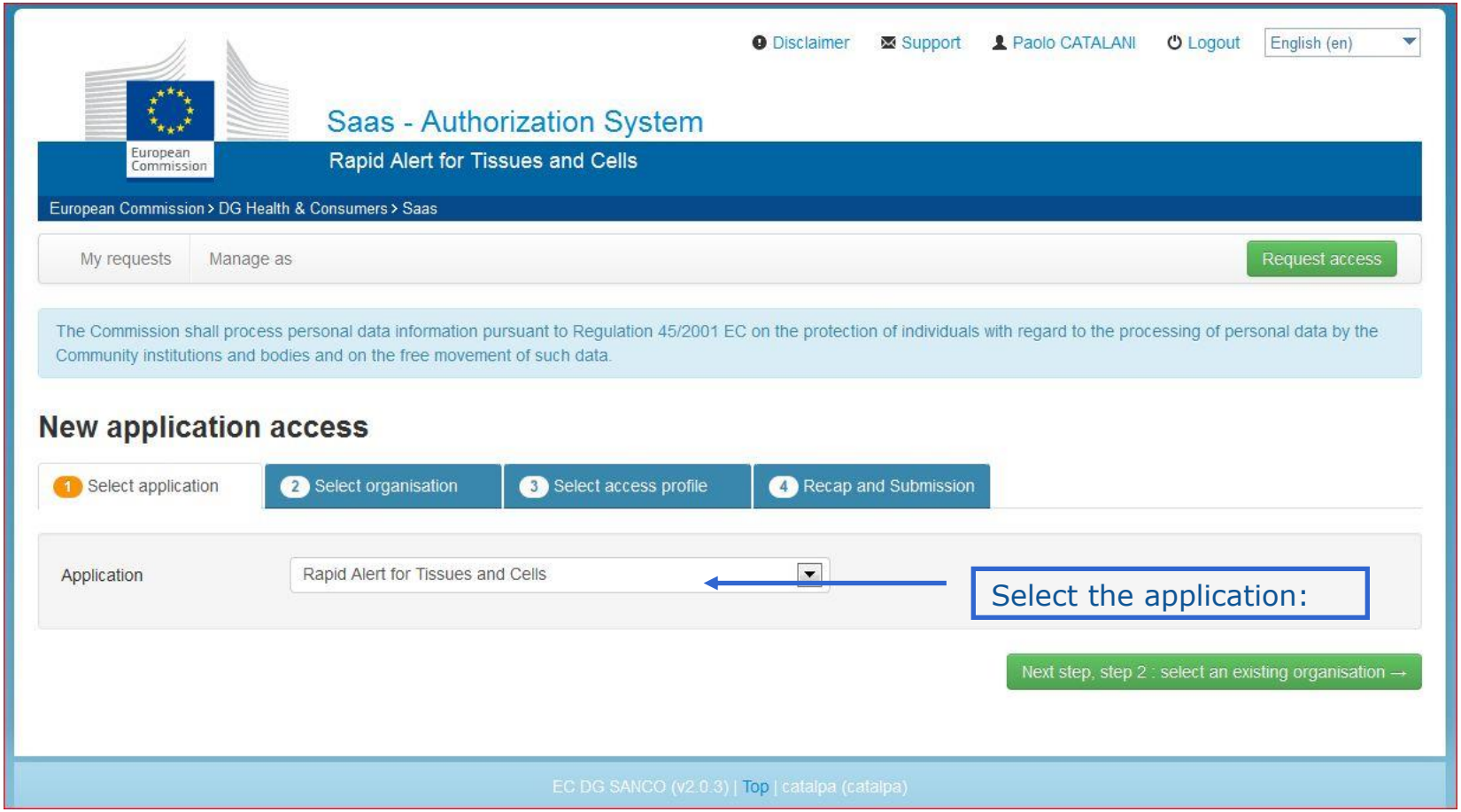
ECAS: FIRST LOGIN (2)



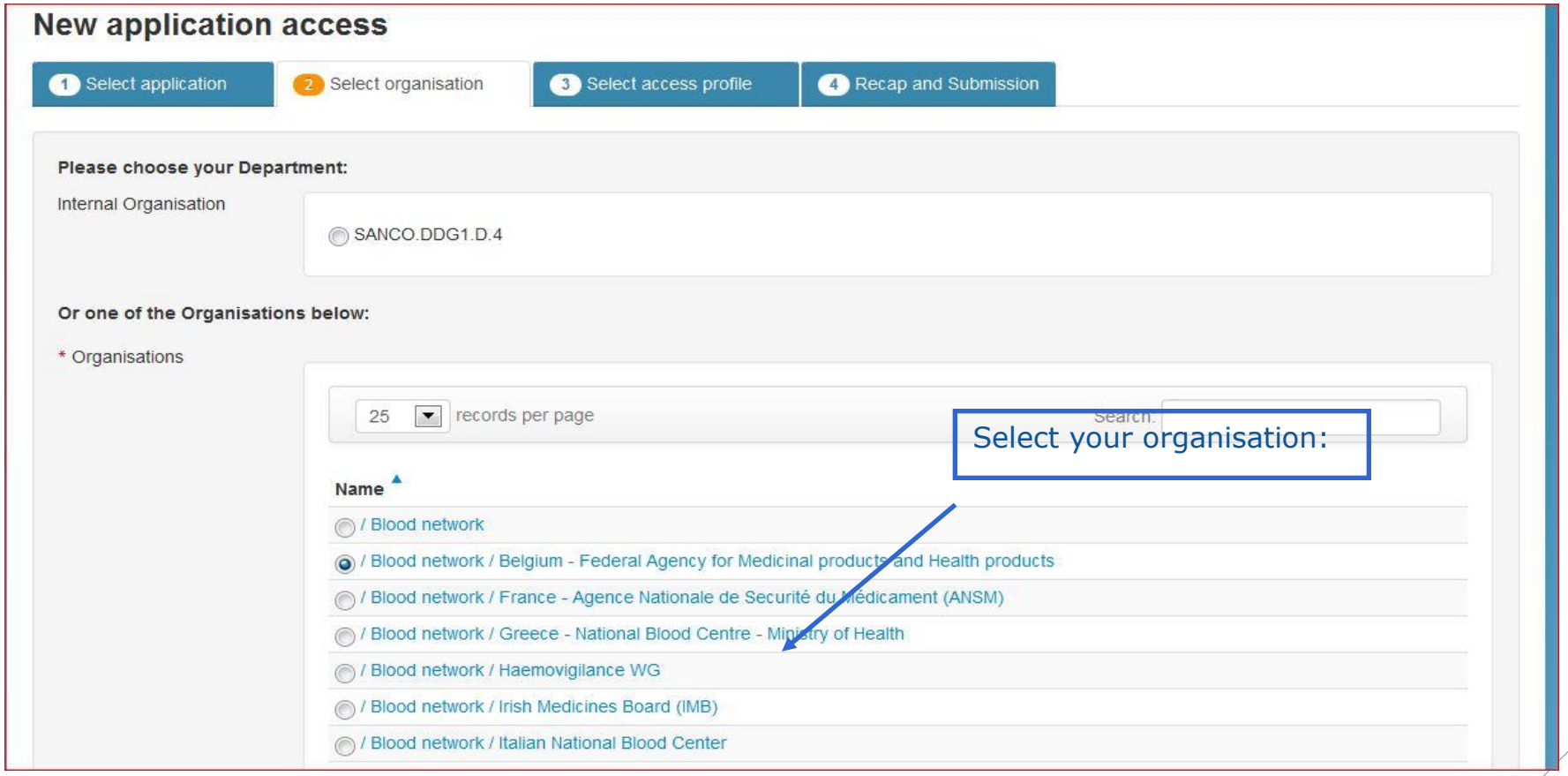
SAAS: REQUEST AN ACCESS TO RAB (1)

- **SAAS: S**ANCO **A**uthentication and **A**uthorisation **S**ystem
- This system provides the user with a profile and access rights for a specific European Commission application, in this case the RAB.
- **Remark:** SAAS provides also administration interfaces to the Local Admin.
- **URL**: **https://webgate.ec.europa.eu/saas**

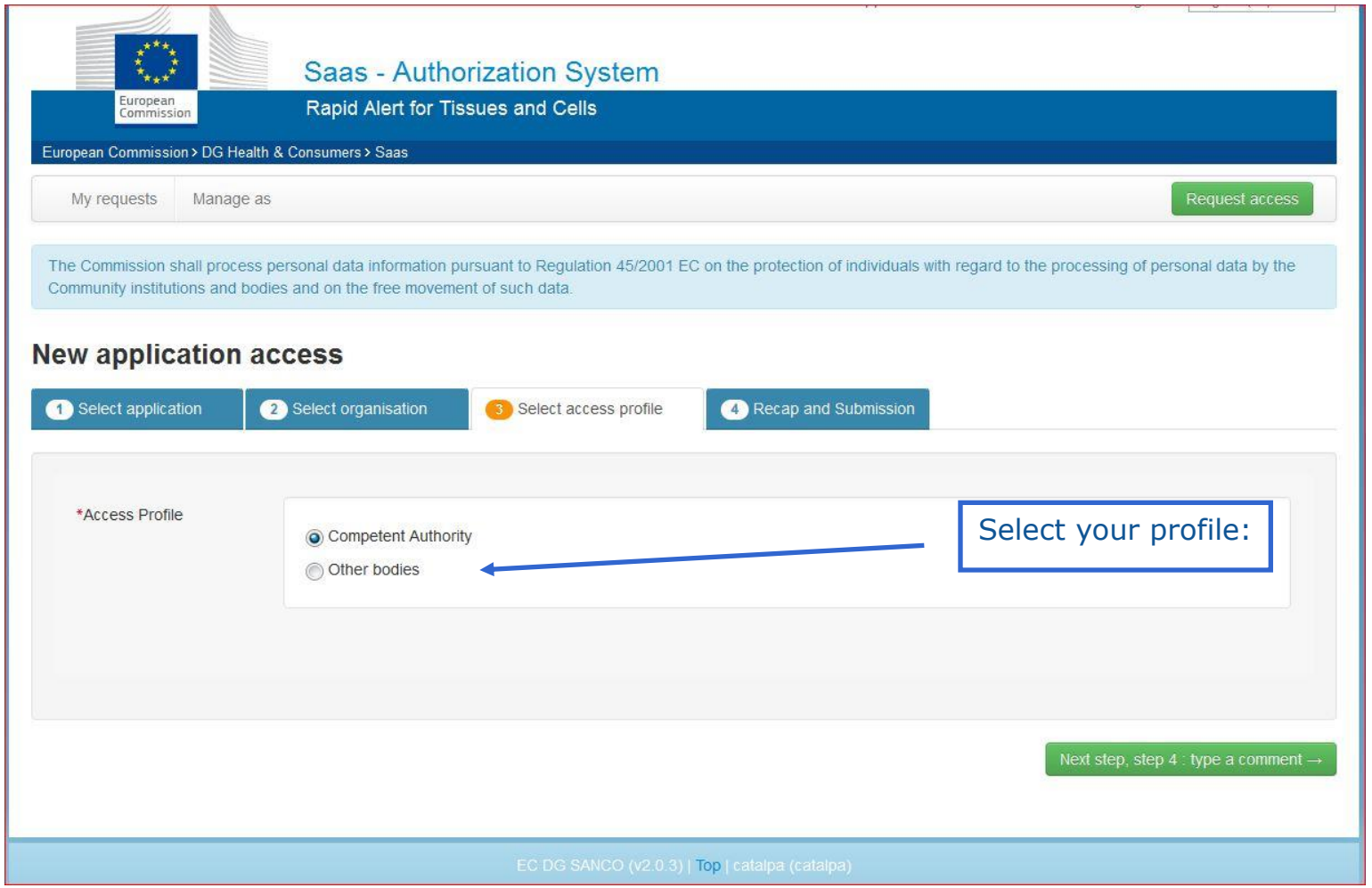
SAAS: REQUEST AN ACCESS TO RAB (2)



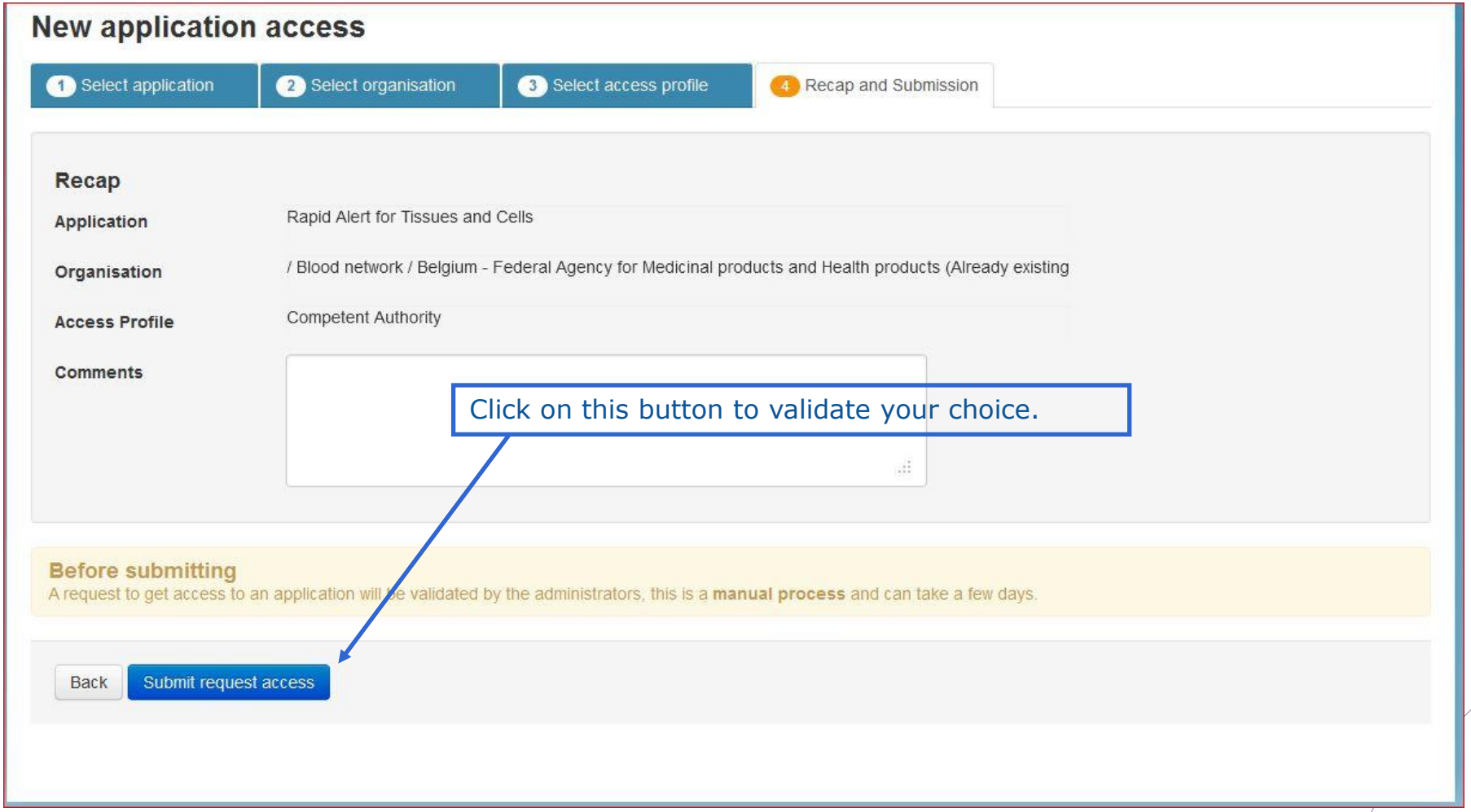
SAAS: REQUEST AN ACCESS TO RAB (3)



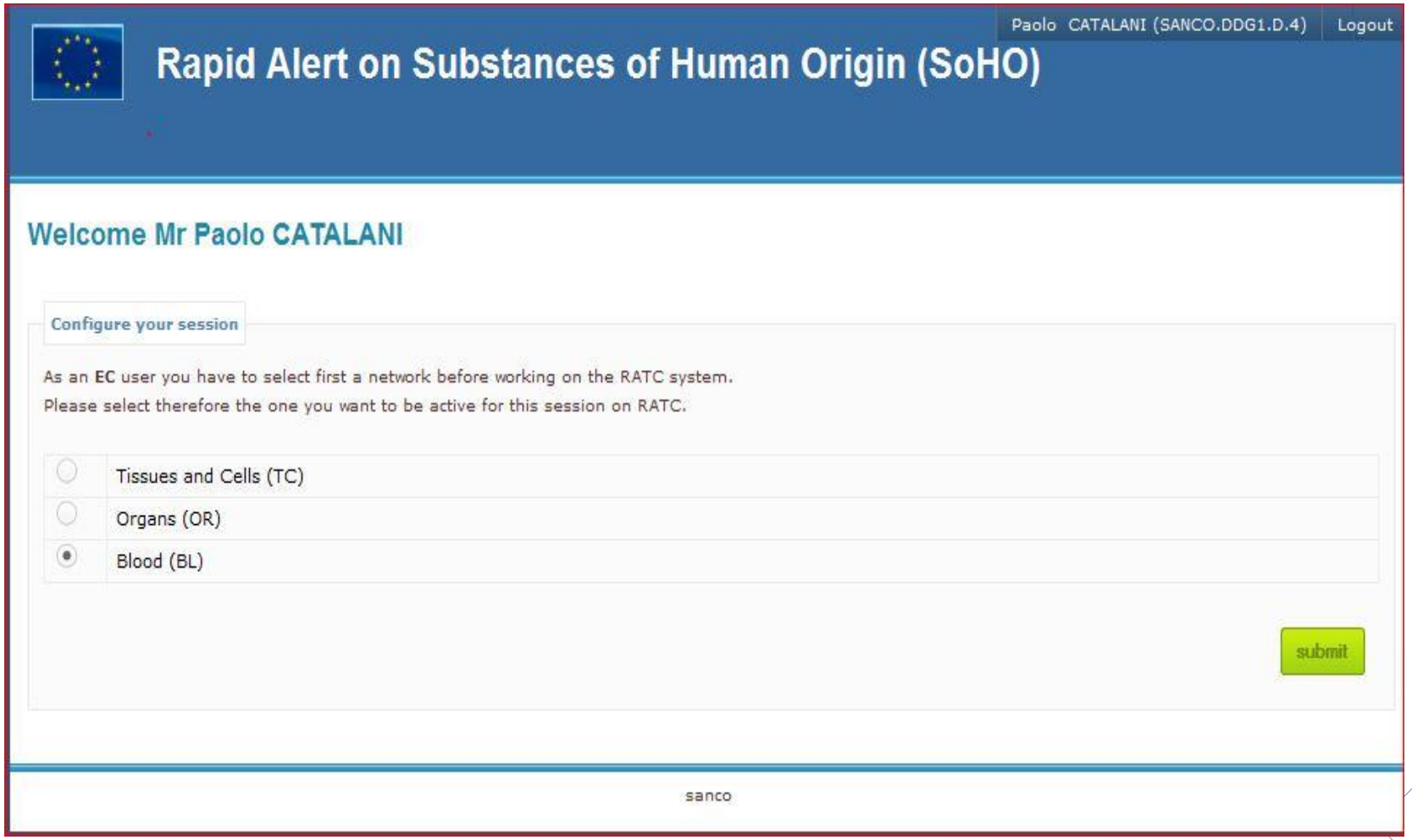
SAAS: REQUEST AN ACCESS TO RAB (4)



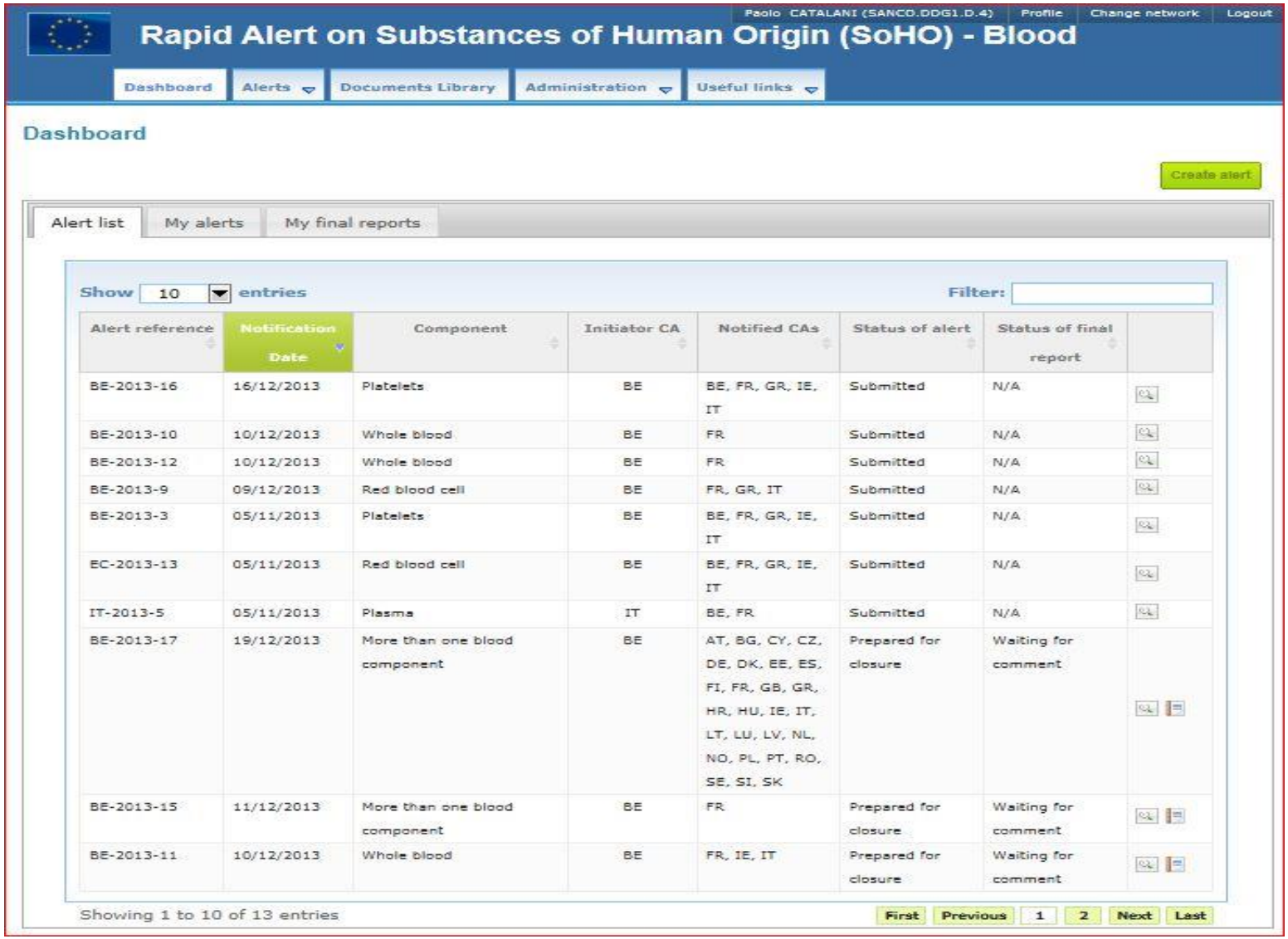
SAAS: REQUEST AN ACCESS TO RAB (5)



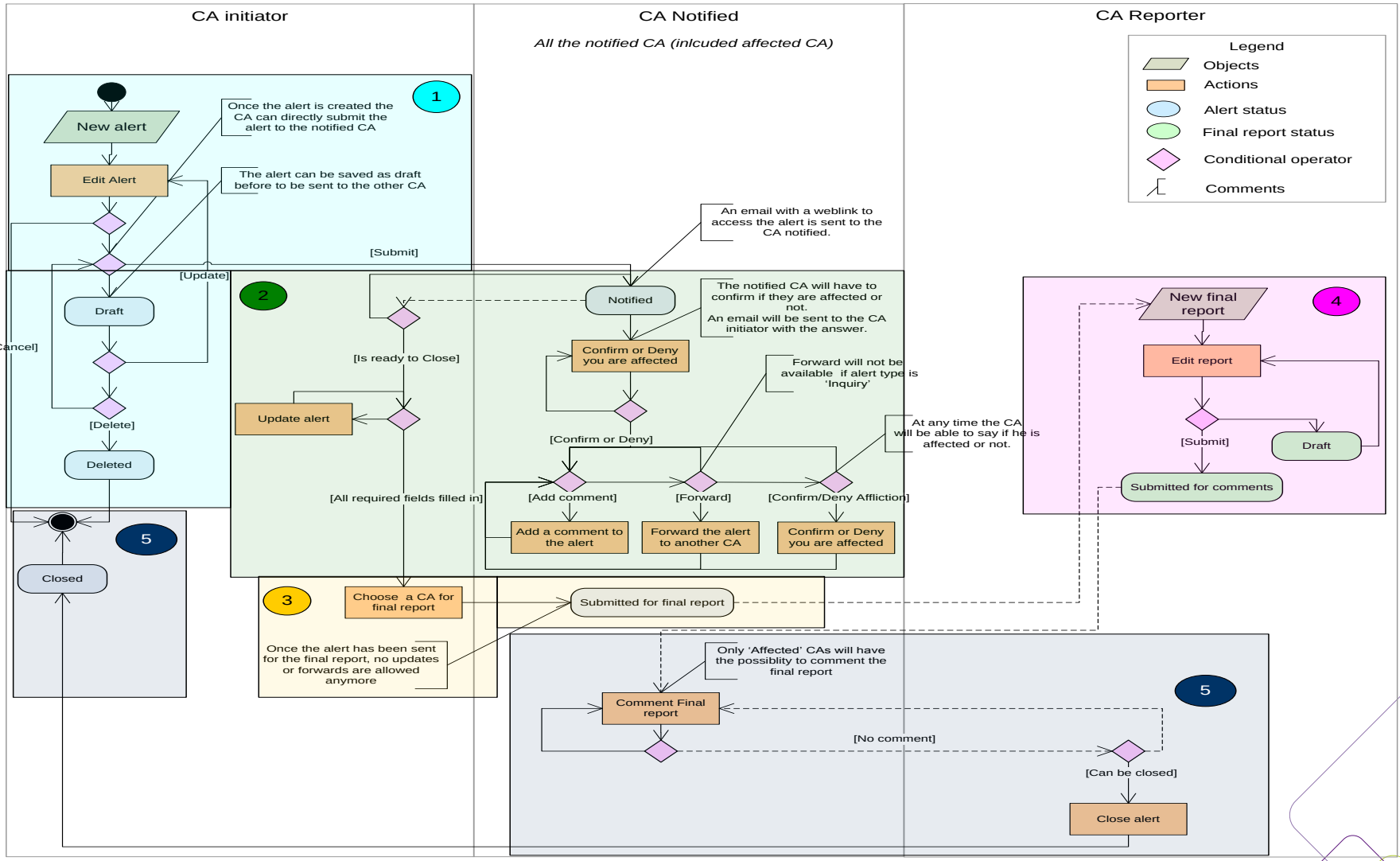
RAPID ALERT ON SOHO - PLATFORM



SYSTEM OVERVIEW: DASHBOARD



ALERTS WORKFLOW



MAIN SYSTEM FEATURES - ALERT

- *Registration*
- Alert

1
- » Create a new alert

2
- » Notify the CA
- » Update an alert
- » Add comments to the alert
- » Confirm or deny affected by the alert
- » Forward the alert to another CA

5
- » Closure of the alert

MAIN SYSTEM FEATURES – FINAL REPORT

- Final report
  - 4 » Complete final report
  - 3 » Selection of the CA reporter
  - 5 » Comments by 'Affected' CA
- Notifications / Reminders (by email)
- Search function
- Document Library

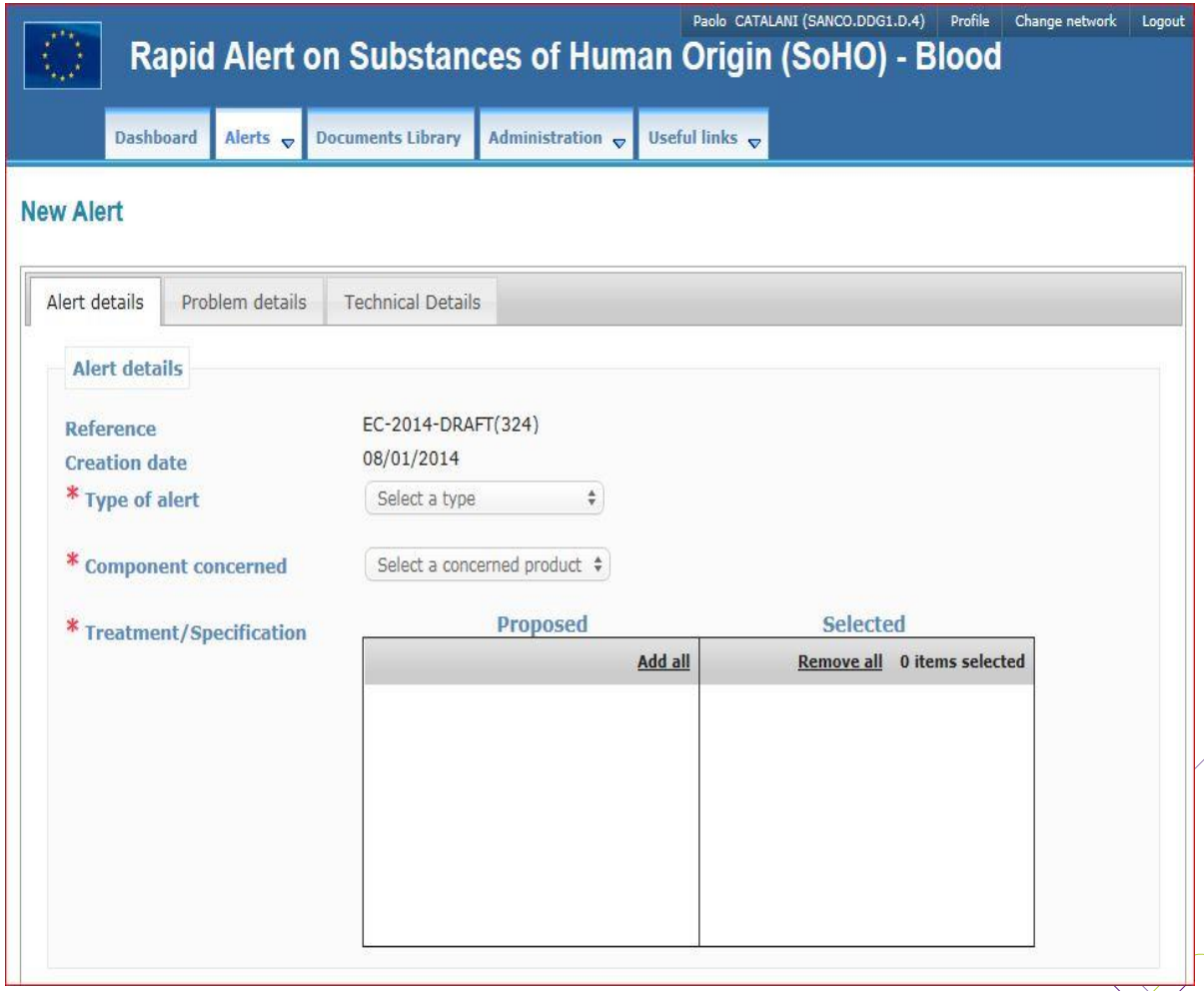
SYSTEM OVERVIEW: NEW ALERT SCREEN (1)

Type of alert:

- Quality and safety
- Information notice
- Epidemiological alert
- Inquiry (only between two Member States)
- Other

Component concerned:

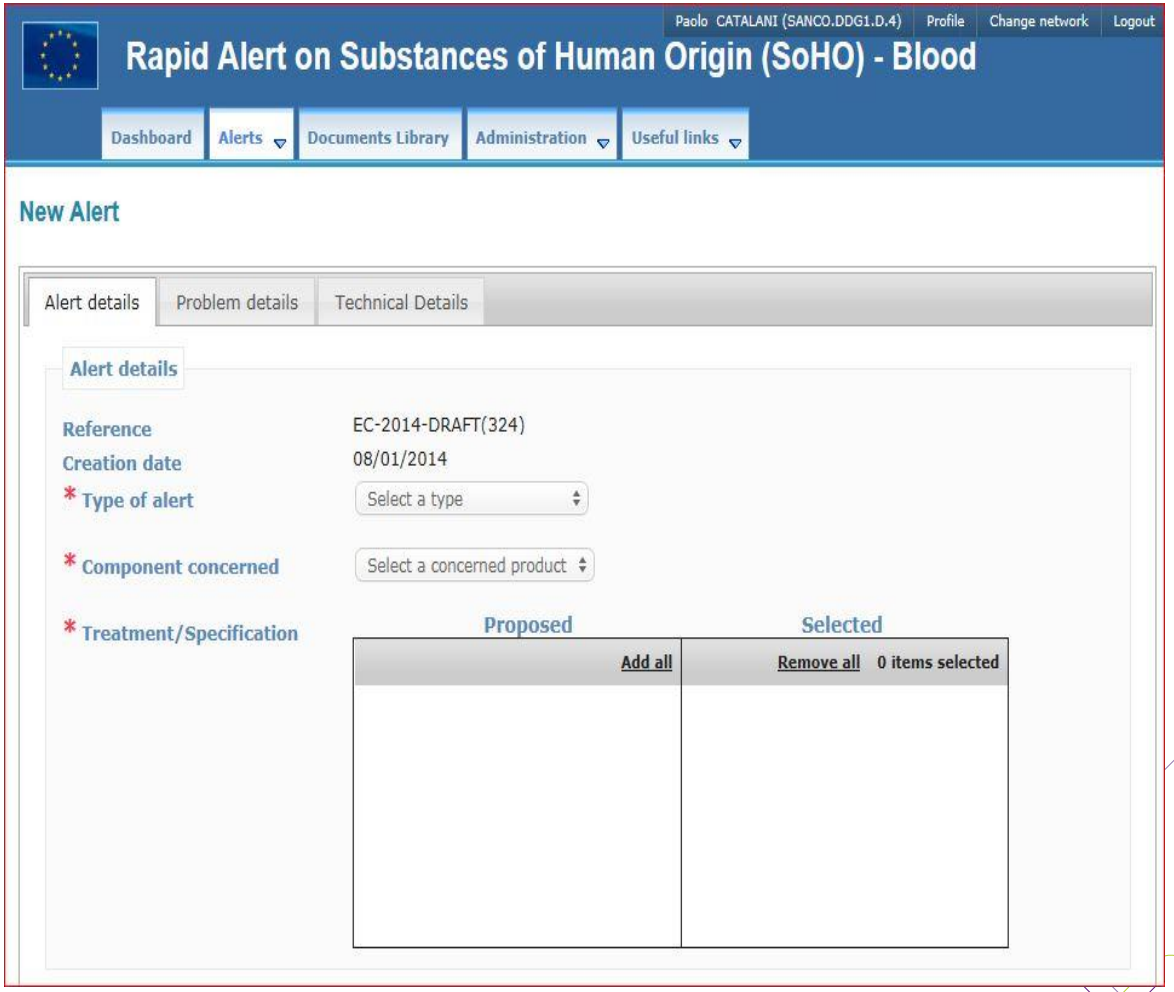
- Plasma
- Platelets
- Whole Blood
- Red Blood Cells
- More than one blood component
- All blood components



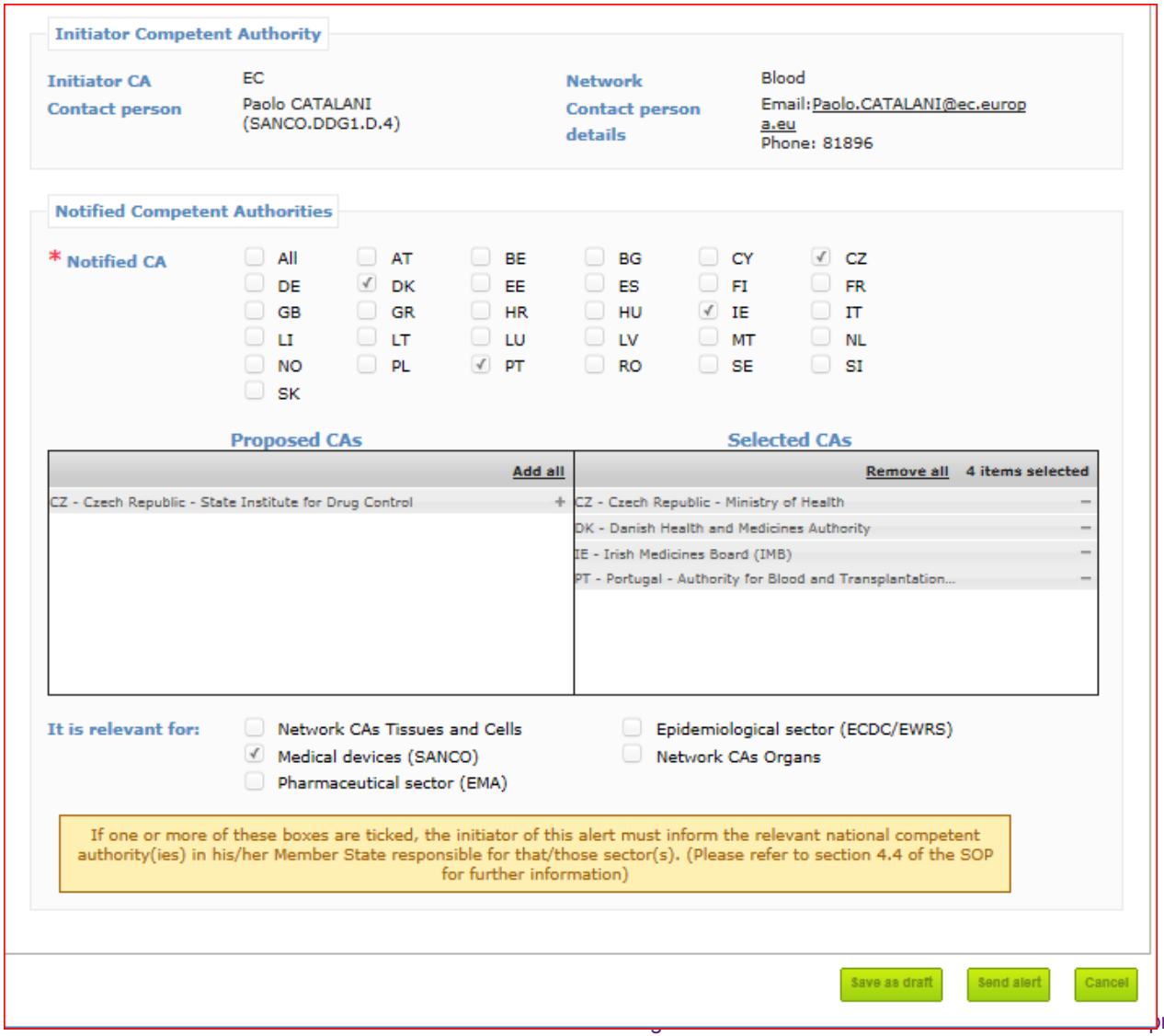
SYSTEM OVERVIEW: NEW ALERT SCREEN (2)

Treatment/Specification:

- Apheresis
- Autologous
- Buffy coat removed
- Cryoprecipitate
- Cryoprecipitate-depleted
- Fresh-frozen plasma
- Frozen/cryopreserved
- Granulocytes
- In additive solution
- Irradiated
- Leucocyte-depleted
- No additional specifications
- Pathogen inactivated
- Pooled
- Recovered
- Single unit
- Thawed
- Washed



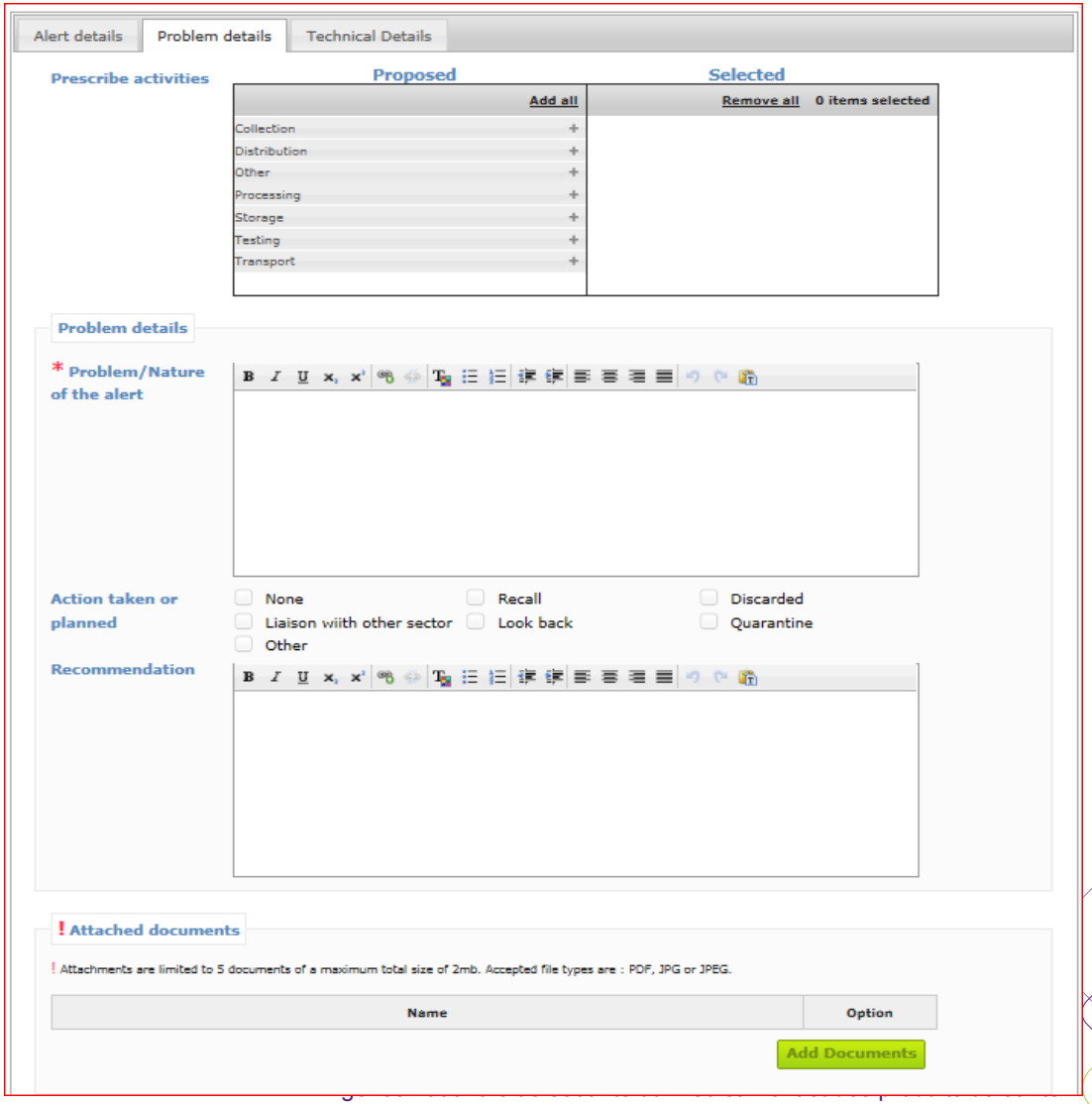
SYSTEM OVERVIEW: ALERT SCREEN (3)



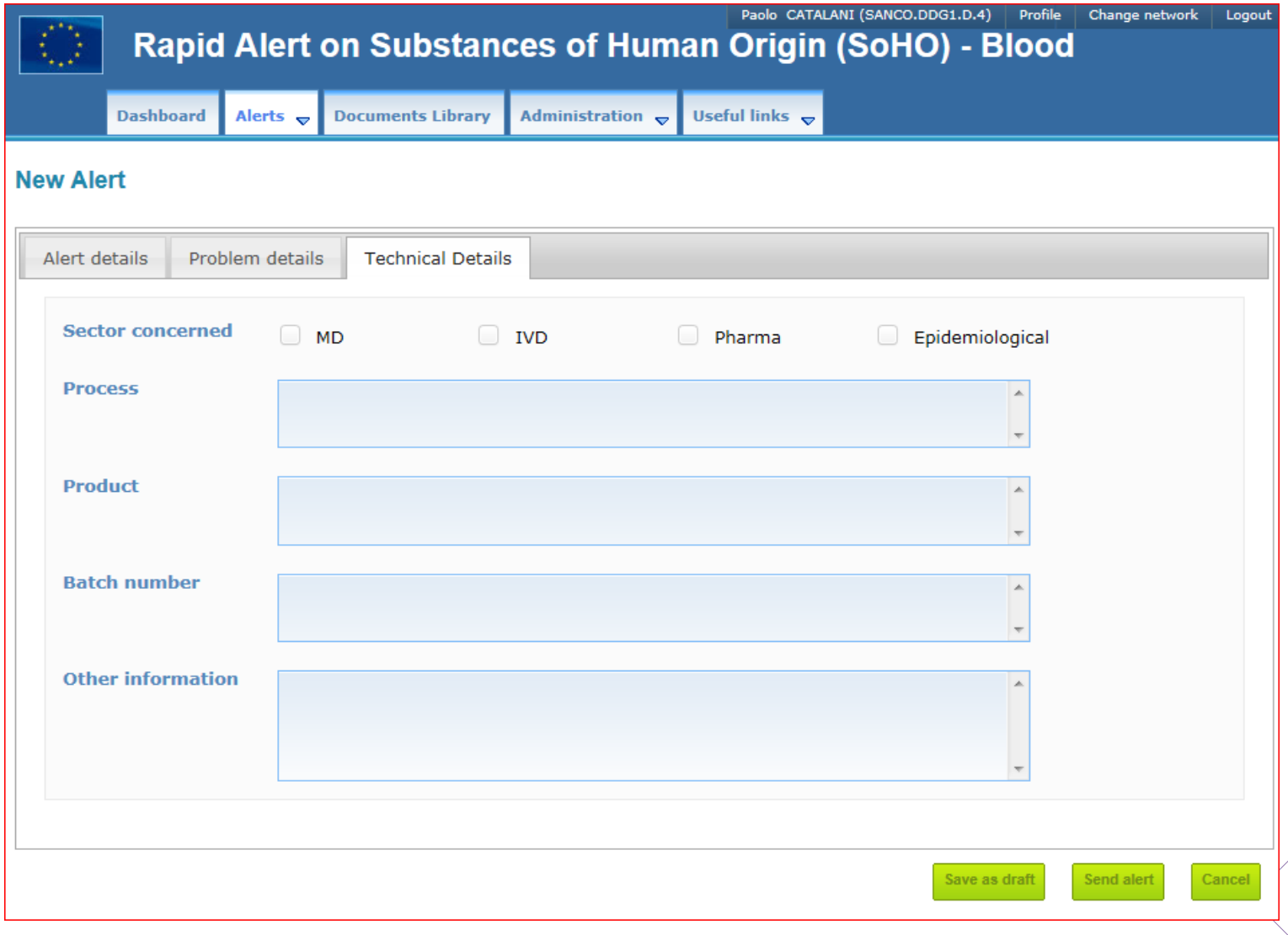
SYSTEM OVERVIEW: NEW ALERT SCREEN (4)

Prescribe activities:

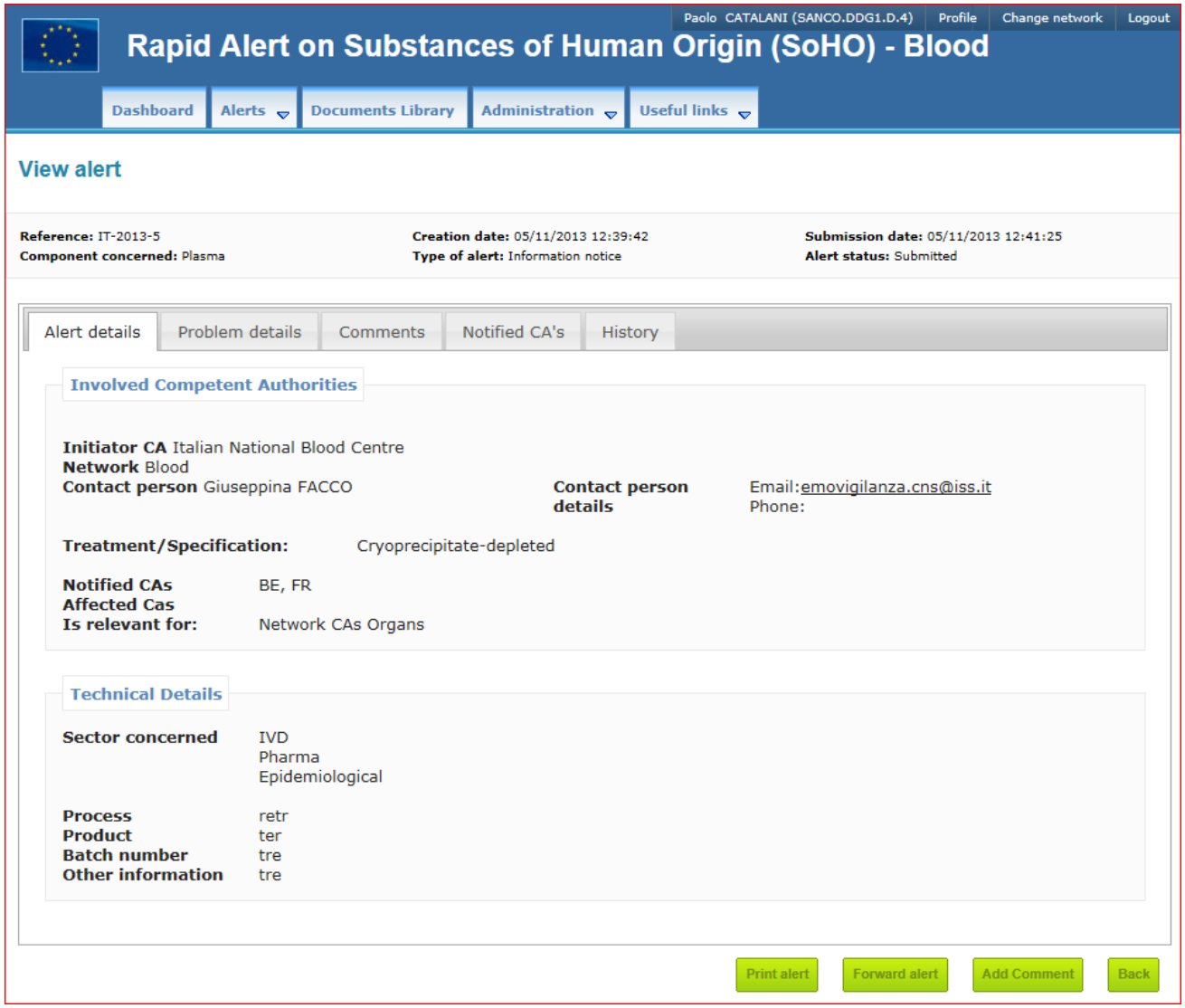
- Collection
- Testing
- Processing
- Storage
- Distribution
- Transport
- Other



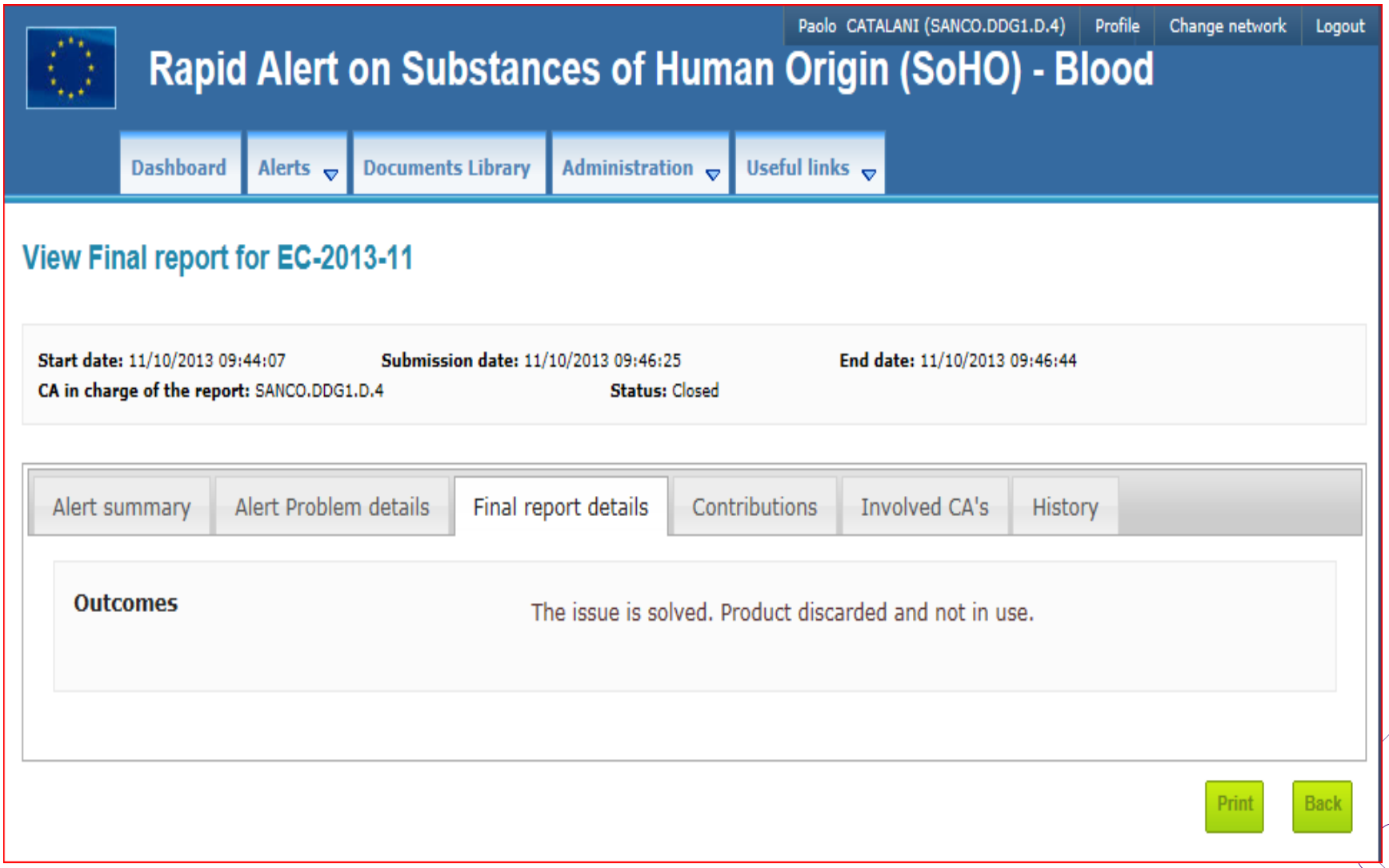
SYSTEM OVERVIEW: NEW ALERT SCREEN (5)



SYSTEM OVERVIEW: ALERT SUMMARY



SYSTEM OVERVIEW: FINAL REPORT DETAILS



NOTIFICATIONS/REMINDERS

- The notification will be done via email and will contain only a link to redirect the user to the alert detail/personal data

- When the user will be notified by email?
  - When the alert is submitted to the CA and other stakeholders
  - Each time a comment is added to the alert (by notified / affected CA)
  - Each time the alert is forwarded to another CA (by notified / affected CA)
  - Each time the alert is updated by the CA initiator
  - When a notified CA confirm or not he is affected by the alert
  - When a CA is assigned to write the final report
  - When the final report is submitted for comments (only to affected CA)
  - When the alert or the final report is closed (all notified CA and other stakeholders)
- When the user will receive a reminder?
  - **5 days** after submission for confirmation to be affected, to remind the **CA** to **confirm or not** (4 times 5 days – after is per default not affected)
  - **10 days** after the submission for comments of the final report, to remind the **CA** to provide comments
  - **Once per month** to remind a Competent Authority to check RATC for news.

RAB DATA PROTECTION

1. Data Protection Notification (linked to RATC)
2. Privacy Statements for Users

RAB SUPPORT

1. **Functional mailbox SANCO-RAB@ec.europa.ec**
2. **Help/Frontdesk dedicated to RAB – technical and operational questions.**
3. **Quick User Manual by January 2014**
4. **SoHO team to provide support on business questions.**

RAB STANDARD OPERATING PROCEDURES (1)

1. RAB SOP as reference document
2. Available to all RAB users
3. In line with the RAB Workflow and User Manual

RAB STANDARD OPERATING PROCEDURES (1)

- **Type of Alerts:** The alerts can be related to:
  - outbreaks of communicable diseases;
  - defects of Medical devices, tests;
  - defects on products used for processing blood or blood products;
  - import and export issues of blood products;
  - Other types.

- **Criteria to report an alert using the RASB are:**
  - Quality/Safety perspective for blood of a serious or potentially serious nature;
  - A known risk to patients, or potential patients, in Member States;
  - With wider public health implications.

RAB CASE STUDIES (HANDS-ON)

1. Scenarios (alerts already submitted)
2. One country each user
3. Play as in a real alert

RAB: NEXT STEPS

1. RAB launched on the first week of February 2014
2. First training course 15th January 2014 in Brussels; 15 Member States
3. Second Training course April 2014.
4. CIRCABC as back-up system
5. Alive project – the platform hosts Blood and T&C

ACKNOWLEDGEMENTS

Thanks to the DG SANCO, Unit D4 Substances of human origin (SoHO) and Tobacco control

Special Thanks to Paolo CATALANI

And to the Experts of the RAB WG

Thank you

Agence nationale de sécurité du médicament et des produits de santé

Avertissement

- Lien d'intérêt : personnel salarié de l'ANSM (opérateur de l'Etat).
- La présente intervention s'inscrit dans un strict respect d'indépendance et d'impartialité de l'ANSM vis-à-vis des autres intervenants.
- Toute utilisation du matériel présenté, doit être soumise à l'approbation préalable de l'ANSM.

Warning

- Link of interest: employee of ANSM (State operator).
- This speech is made under strict compliance with the independence and impartiality of ANSM as regards other speakers.
- Any further use of this material must be submitted to ANSM prior approval.