



9th EHS, Dublin: 27.02.2007 – WS 3.

# Training session on EHN-Website and Rapid Alert

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- Introduction
- Incident and near incident reporting for MD as seen by manufacturers (*Dr. Ruth Clayton, EUCOMED; Gambro*)
- European Haemovigilance Programme for Intercept treated platelets  
(*Dr Larry Corash, Cerus*)
- Rapid Alert as seen by users  
(*Dr. Lisette Hauser, EFS*)
- Training on the new EHN-website (including RAS)  
(*Dr. Charles Salpeteur, EHN*)
- Discussion



## History of this WS:

- rapid alerts in the past
- 8<sup>th</sup> EHS in Porto: Session on rapid alert
- rapid alert of 14.04.2006
- reaction of the manufacturer
- meeting with EUCOMED – BSG (30.05.2006)
- changes within EHS (web, OCPs)
- 9<sup>th</sup> EHS in Dublin: Session on rapid alert
- broadening of the scope



## Objectives of the WS:

- stress the importance of rapid alert
- show the common interest of the users and the manufacturers with EHN-RAS
- stimulate the participation in EHN-RAS
- train OCPs in the correct use of EHN-RAS
- come up with proposals to improve EHN-RAS



## Question:

- How many countries represented in the audience?
- Who is a member of EHN?
- Who is an OCP? **7 / 25**
- Who has already launched an alert in the past? **4 / 7**
- Who could possibly have launched an alert, but did not for whatever reason? **6 / 7**



# EHN : European Haemovigilance Network





## EHN: Membership

### **21 members:**

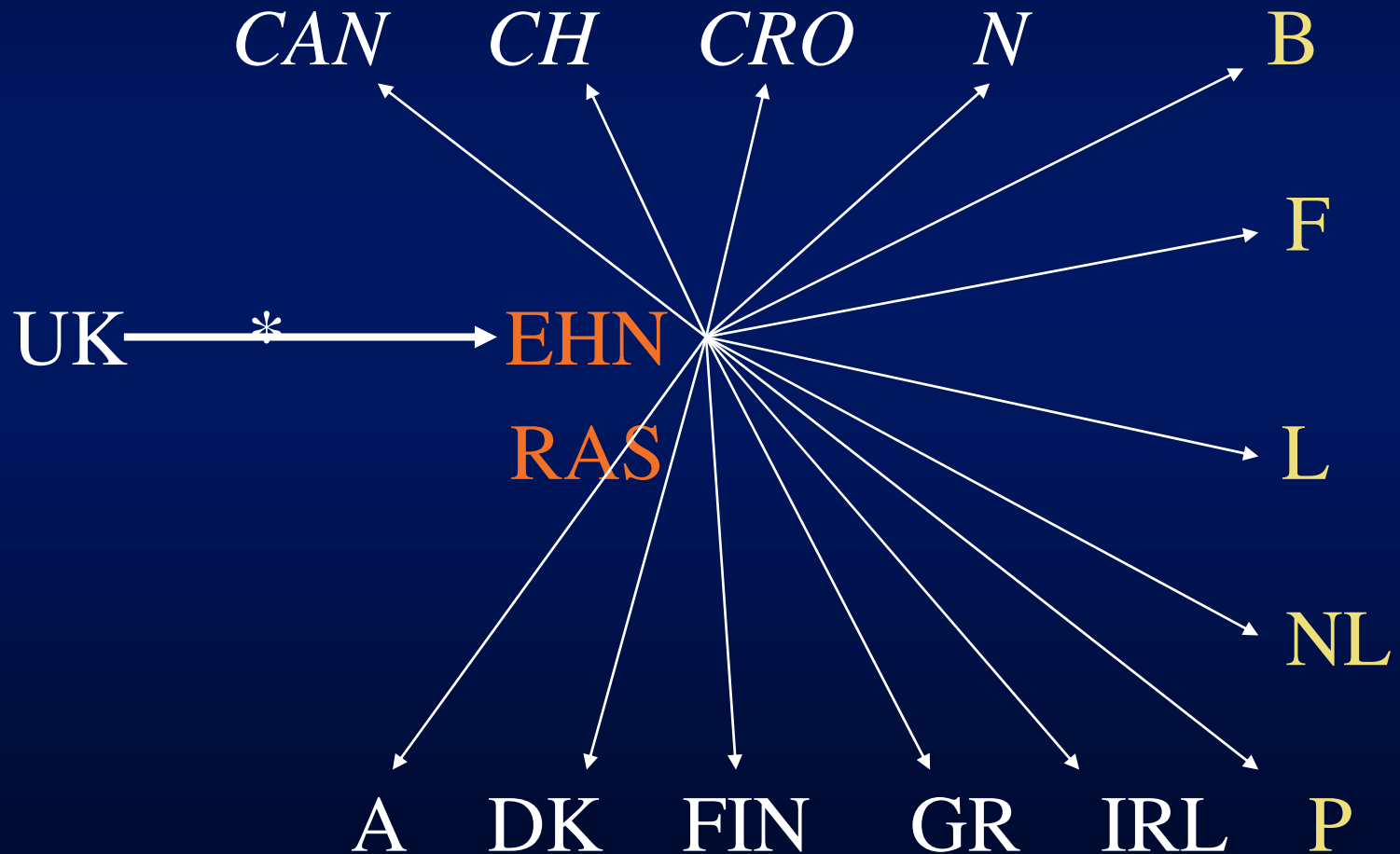
- Austria
- Belgium
- *Canada*
- *Croatia*
- Denmark
- Finland
- France
- Greece
- Ireland
- Luxembourg
- The Netherlands
- *Norway*
- Portugal
- *Switzerland*
- United Kingdom

### Recent adherents:

*Iceland, Malta, New Zealand, Singapore, Slovenia, Spain*

# EHN – RAS / Rapid Alert: alerting / warning

+ : ICE, MT, NZ, SIN, SLO, SP

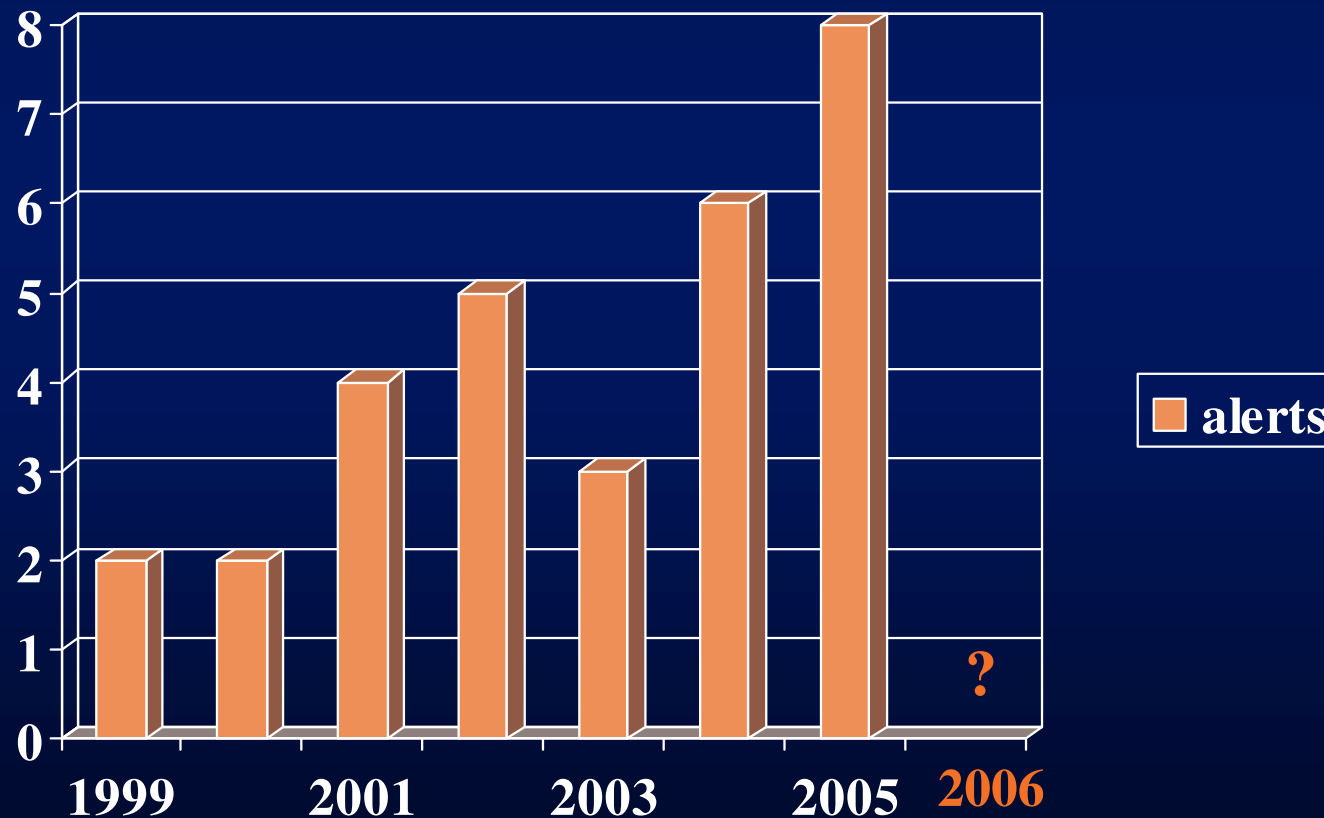


## **EHN-RAS has been used on different occasions:**

- /// appearance of **clusters of clinical signs / symptoms/ reactions** after transfusion
- /// hidden or apparent defects of **disposable material** used in transfusion (ex.: leakages of filter housings, holes in collection bags, defects in apheresis material, failure to pass lot validation\*, ...)
- /// problems with **equipment**
- /// deficiencies with **reagents** (ex.: ELISA tests giving false negative results - sensitivity problem, giving a high number of false positive results - specificity problem; blood grouping antisera failing to give the correct phenotype; immuno-haematological in vitro diagnostics failing to detect weak allo-antibodies,...)

Alerts:

- total (overall): > 30





## What happened in 2006?

- new EHN-website
- new RAS module
- changes in OCPs
- ? fading enthusiasm
- ? better quality of materials (disposables, reagents,...)
- ???

## Crucial role of the OCPs

(Official Contact Persons –  
nominated or nationally agreed individuals,  
by country, by cNA, by organisation):

- **EHN-RAS is a network of OCPs**

In the context of RAS, they have the functions of :

- entry into the system
- exit
- filter
- dispatch

**Their role is vital: if OCPs do not participate  
ACTIVELY, the system is not working**

Eucomed – Blood Safety Group (BSG)

- Collection bags
- Separators
- Storage bags
- Solutions
- Treatments
- IT software
- In-vitro diagnostic testing (through EDMA)

# WS 3. at 9<sup>th</sup> EHS: Incident and near incident– R. Clayton

Blood 2002/98 & 2005/61

MDD 93/42 & IVD 98/79

Donor  
recruitment /  
management

Apheresis  
collections

Manual  
Collection

Component  
Lab + LR +  
Safety

Testing  
Processing

Storage  
Distribution

Transfusion  
to patient

Information technology



Blood Establishment  
Designation, authorisation, accreditation.  
licence

Hospital Blood Bank

Qualified personnel, quality systems, documentation, traceability,  
SAE reporting, data protection

## Medical Device Directive 93/42/EEC

### • Article 10

#### Information on incidents occurring following placing of devices on the market

1. Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Directive, regarding the incidents mentioned below involving a Class I, IIa, IIb or III device is recorded and evaluated centrally:

(a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic recall of devices of the same type by the manufacturer.

2. Where a Member State requires medical practitioners or the medical institutions to inform the competent authorities of any incidents referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorized representative established in the Community, is also informed of the incident.

3. After carrying out an assessment, if possible together with the manufacturer, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of the incidents referred to in paragraph 1 for which relevant measures have been taken or are contemplated.

- Central evaluation

- Malfunction, inadequacy of labeling that might lead to or might have led to death or serious deterioration in health

- Manufacturer informed

- Inform Commission and Member States



## MEDDEV guidance – 2.12-1 rev 4

- Information supplied with report:
  - Opinion of health-care professionals
  - Results of manufacturer's preliminary assessment
  - Evidence of previous similar incidents
  - Other evidence held by the manufacturer

### Time frame for reporting to authorities

- MAXIMUM

Incidents – 10 days

Near incidents – 30 days



## Actions following report

### Manufacturer

- additional surveillance
- advisory notice
- corrective action – production, in use
- recall

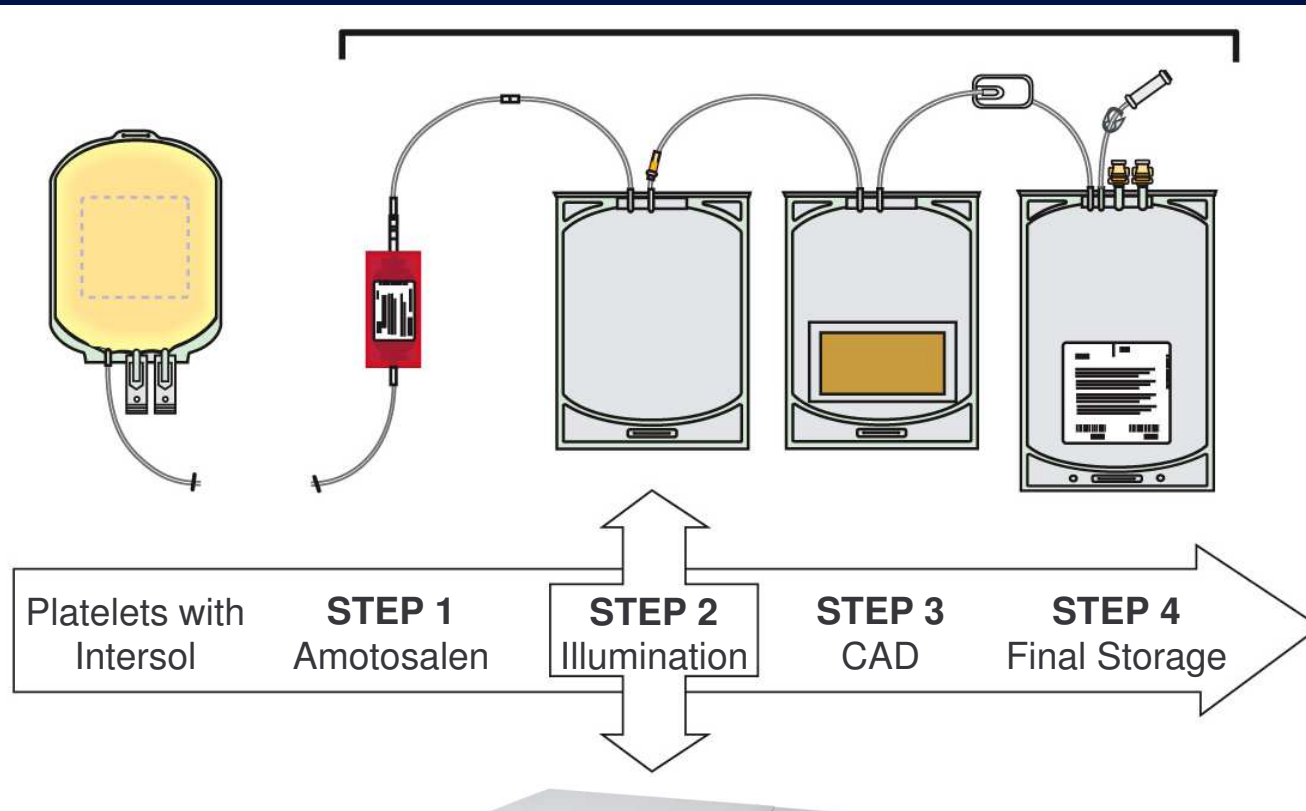
### Competent Authority

- advisory notice
- gathering more information
- recommendations to manufacturers
- Commission and other Competent Authorities informed
- Notified Body consultations
- Further user education + recommendations

- manufacturers operate in a heavily regulated environment
- manufacturers have to comply with numerous legal requirements
- they have clear obligations and responsibilities in the context of incidents and near-incidents
- ... but that does not exclude that they see also a benefit in collaborating with EHN and EHN-RAS

# WS 3. at 9<sup>th</sup> EHS: INTERCEPT Platelet Processing Set – L. Corash

## Integrated processing set



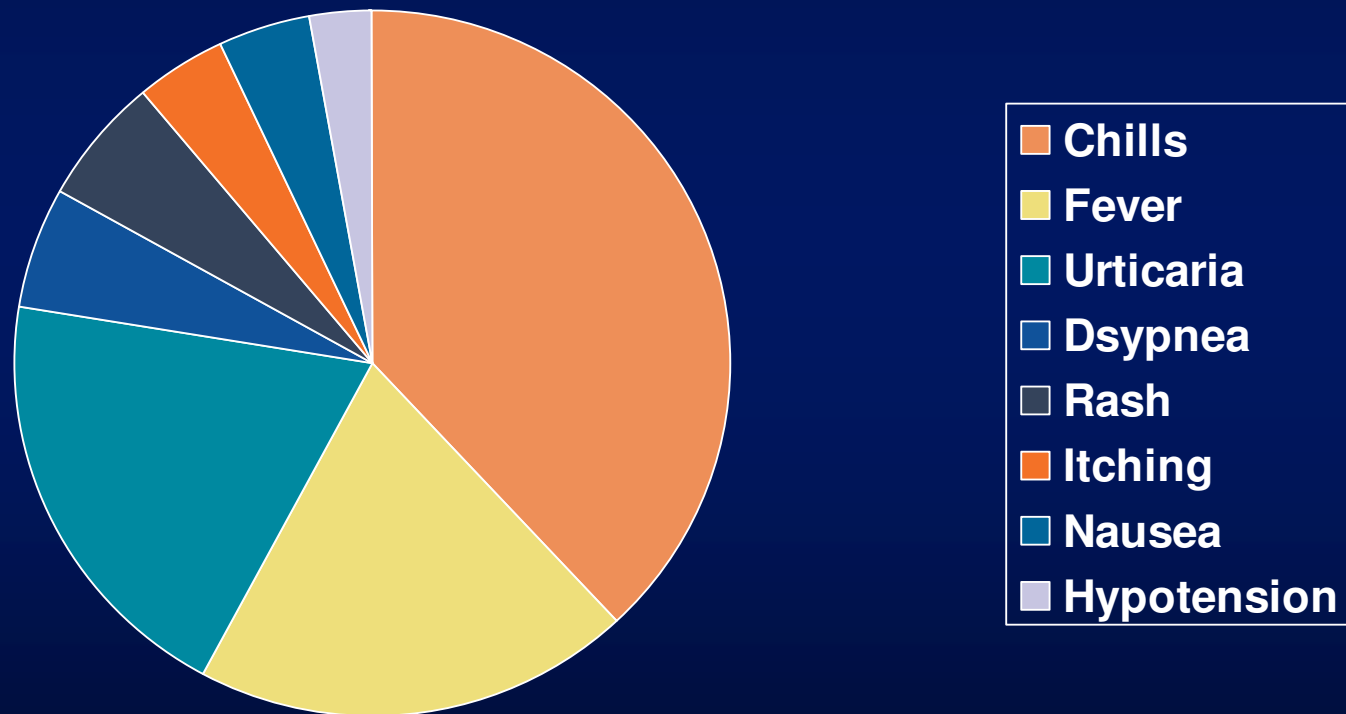
- INTERCEPT Platelets
  - for transfusion support of patients requiring platelet transfusions according to clinical practice guidelines. INTERCEPT Platelets are not clinically different from untreated platelets.<sup>1</sup>
- CE Mark 2002
- AFSSAPS Product Approval 2005
- PEI Marketing Authorization 2007

<sup>1</sup>Approved product claims.

- Prospective observational studies: post marketing
- Obligatory reporting
  - Internet based system
- Characterize safety in a broad patient population
- Follow EHN parameters
  - EFS format

- HV-1: 5,000 transfusions
  - Multi-center, multi-national
- HV-2: 7,000 transfusions
  - 2,500 transfusions, EFS centers
  - 5,000 transfusions, non-EFS centers
- Pediatric Study
  - University of Ghent: 500 transfusions
- HV-3: 5,000 transfusions
  - Multi-center, multi-national
  - Potential to extend
- HV - La Reunion

# Clinical diagnosis: based on 75 reactions in HV-1 – L. Corash



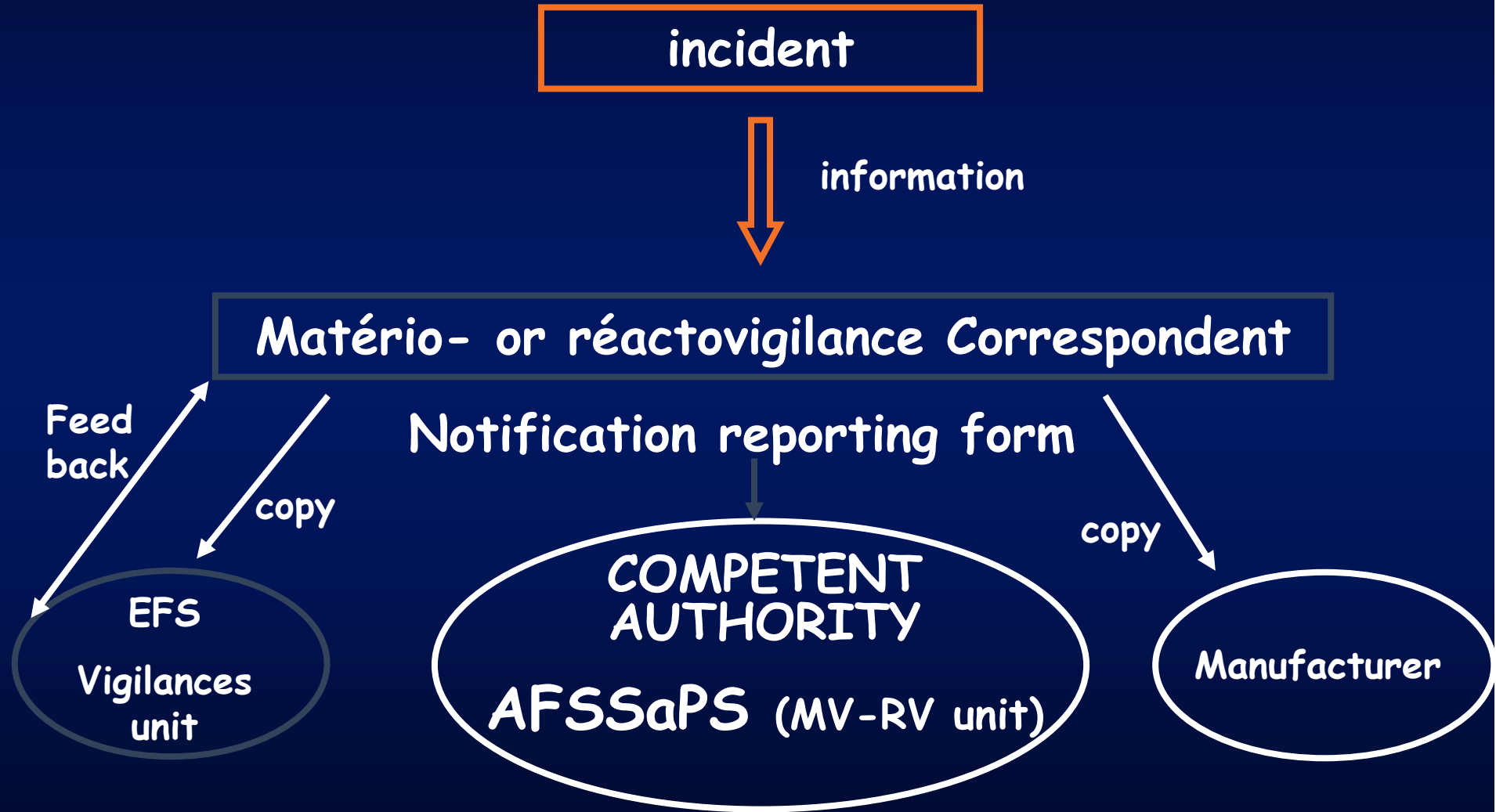


## Pediatric experience: clinical response – L. Corash

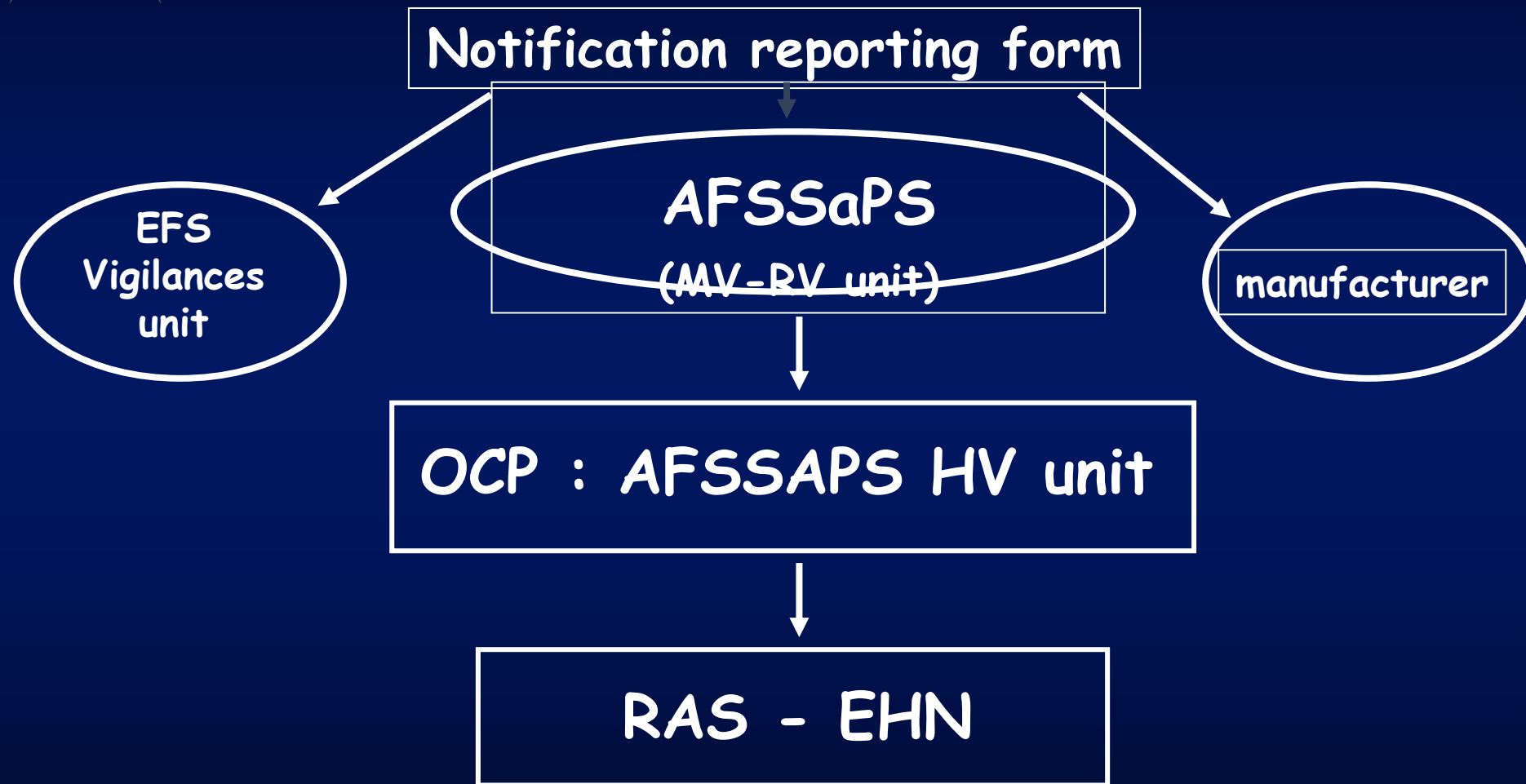
- Hemostatic control was effective
- No post-transfusion bacterial infections reported
  - INTERCEPT replaced bacterial testing
- No TA – GVHD
  - INTERCEPT replaced gamma irradiation
- 8 transfusion reactions in 7 patients
  - **7 fever**
  - **1 urticaria**

- Intercept: novel technology
- extensive clinical studies prior to approval
- extended haemovigilance post-marketing
- % of adverse reactions low ( < 1% )  
(but very rare reactions, side-effects may only become apparent after a large no. of tx)  
(? long term effects)
- Intercept PLT appear to be safe and efficacious

WS 3. at 9<sup>th</sup> EHS: rapid alert in France – L. Hauser  
MATÉRIO-REACTOVIGILANCE - EFS NOTIFICATION



# MATERIO-REACTOVIGILANCE NOTIFICATION ON RAS - EHN

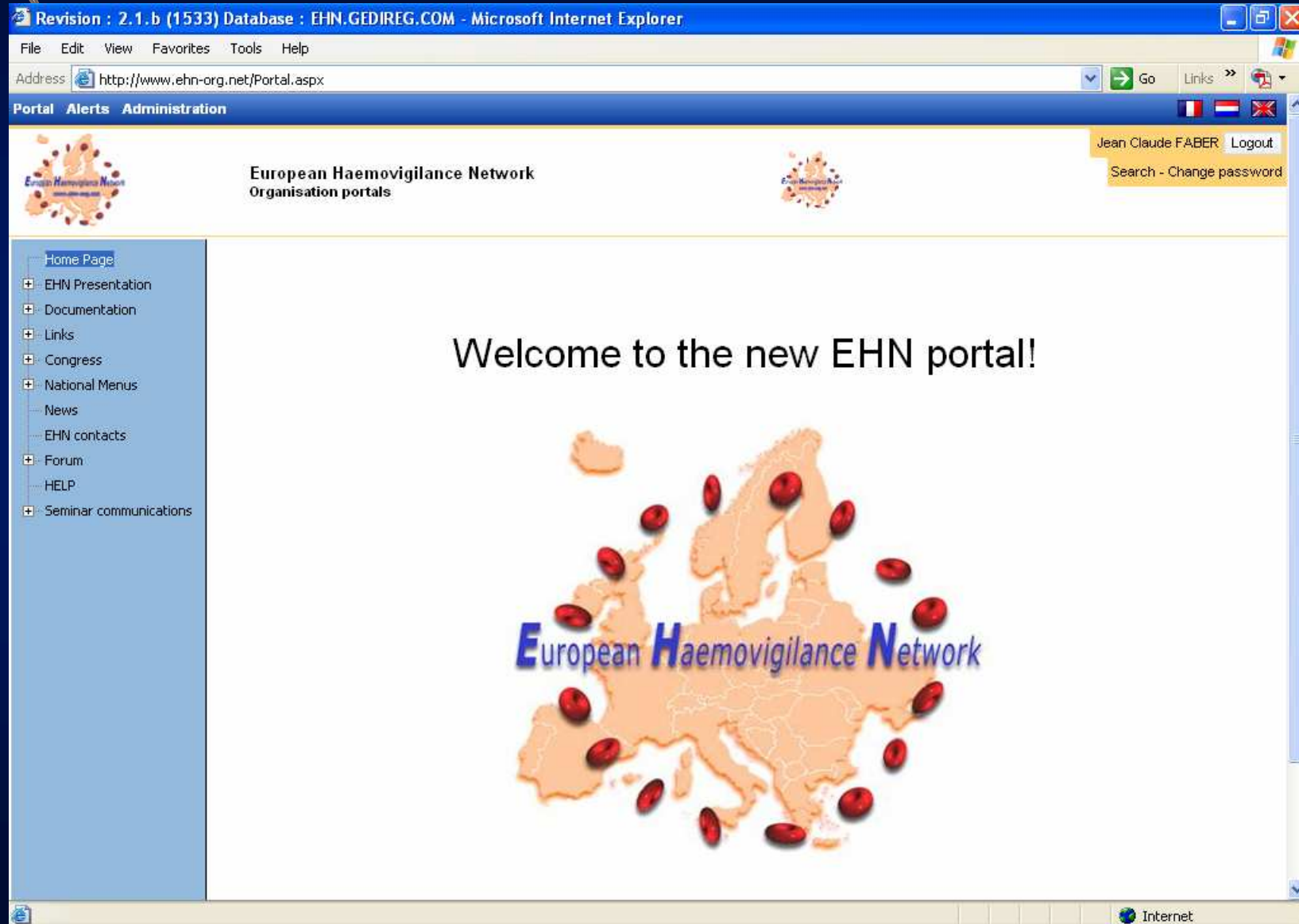


- EFS (producer of BC): recipient adverse reactions, donor adverse reactions, matériovigilance, réactovigilance and biovigilance incidents
- different actors: situation in France  
OCP in AFSSAPS (cNA), not within EFS (producer)
- trigger: rapid alert if “important problem”  
(what is important?)

France (2005):

- 40 cases of MV
- 30 cases of RV
- ... so there is a huge potential of information that may be shared with EHN- OCPs

# WS 3. at 9<sup>th</sup> EHS: Training on the new website – C. Salpeteur



The screenshot shows a Microsoft Internet Explorer browser window displaying the EHN portal. The address bar shows the URL <http://www.ehn-org.net/Portal.aspx>. The browser title is "Revision : 2.1. b (1533) Database : EHN.GEDIREG.COM - Microsoft Internet Explorer". The page content includes a navigation menu on the left with items like "Home Page", "EHN Presentation", "Documentation", "Links", "Congress", "National Menus", "News", "EHN contacts", "Forum", "HELP", and "Seminar communications". The main content area features the text "Welcome to the new EHN portal!" and a large graphic of a map of Europe with red blood cells scattered around it, with the text "European Haemovigilance Network" overlaid. The user is logged in as "Jean Claude FABER" and can click "Logout" or "Search - Change password".

Revision : 2.1. b (1533) Database : EHN.GEDIREG.COM - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://www.ehn-org.net/Portal.aspx> Go Links

Portal Alerts Administration

Jean Claude FABER Logout

Search - Change password

European Haemovigilance Network  
Organisation portals

Welcome to the new EHN portal!

European Haemovigilance Network

Internet

# WS 3. at 9<sup>th</sup> EHS: Training on the new website – C. Salpeteur

Revision : 2.1. b (1533) Database : EHN.GEDIREG.COM - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://www.ehn-org.net/Alerts.aspx> Go Links

Portal Alerts Administration

Jean Claude FABER Logout  
Search - Change password

European Haemovigilance Network  
Organisation portals

Alerts  
Inread  
Read  
My reports  
Addresses

Save and send alert Cancel

**(This report is for your information only and does not suggest any action.)**

Reference : LU/2007-02-25/10:37:36

Date : \* 25/02/2007

Subject : \*

Type :  
 Haemovigilance  Materiovigilance

Description :

Attachment : Browse...

**Materiovigilance :**

Product denomination :

Product address :

\* Required Field

Internet

- ❑ RAS page is very easy to handle
- ❑ it has additional facilities (export function, attachments,...)
- ❑ it will include a tick box
- ❑ “Have you informed the implicated company that a rapid alert has been launched concerning a problem with one of their materials?”

N.B. The list of industry contacts will be provided to EHN and updated by EUCOMED

- new website is user friendly
- its structure is logical and transparent
- it is robust
- it has very flexible
- it has different levels of access and rights
- the interventions by the webmaster are reduced to a minimum
- it can be easily adapted by EHN-administrators
- ... the tool is ready: it can and should be used  
by **YOU!**



## Crucial role of the OCPs :

For EHN-RAS, they ensure multiple roles:

- Entrance
- Exit
- Filter
- Dispatching
- Animation

*... a vital role: if OCPs do not participate ACTIVELY,  
EHN-RAS is not working*



## OCPs ?

- Do they have direct access to the national system?
- Do they have access to detailed information?
- Do they have authority to take an information from the national system and put it on EHN-RAS?
- Do they have authority to take an information from EHN-RAS and put it on the national system?
- Do they have time to participate in EHN-RAS?
- Do they know about the importance of circulating the national alerts through EHN-RAS?

- OCPs should develop a natural **reflex** to share information on national alerts / recalls with their international colleagues
- a **monthly** reminder could be sent by the EHN Secretary (e-mail)
- OCPs should make sure that they **recieve information on recalls, withdrawals, alerts,...** in their own national system
- OCPs should include **voluntary recalls** by industry in the alerts
- OCPs should « feed » more systematically **national alerts / recalls into the EHN-RAS**



*Proposals to improve RAS:*

- *in case of an alert, the **manufacturer** may be given a maximum of 24 hrs to submit a written statement / position*
- **in case of an alert, the **manufacturer** should receive an **e-mail** at the same time OCPs receive the alert**



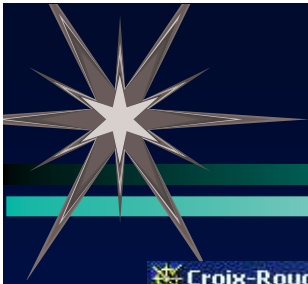
*Proposals to improve RAS:*

- organise regular **training** sessions for OCPs
- redefine the frame for rapid alerts  
(what should be circulated, what not)
- review the role of the OCP
- revisit the concept of a single OCP per member organisation



## Rapid Alert (RAS): recommendations

- EHN-RAS can be improved
- different measures are proposed
- EHN-RAS is and remains an important tool in the context of quality and safety of blood transfusion
- ...: *opening speech from the Minister of Health of Ireland, who specifically mentioned the importance of rapid alert*



# Luxembourg Red Cross

<http://www.croix-rouge.lu>



Croix-Rouge luxembourgeoise - Santé - Centre de Transfusion Sanguine - Netscape

Datei Bearbeiten Ansicht Gehe Communicator Hilfe

Zurück Vor Neu laden Anfang Suchen Guide Drucken Sicherheit Shop Stop

Lesezeichen Adresse: [http://www.croix-rouge.lu/sante/link\\_cts.htm](http://www.croix-rouge.lu/sante/link_cts.htm) Verwandte Objek

## Croix-Rouge luxembourgeoise

Accueil Jeunesse Santé Social International

Santé

- Aidsberodung
- Service ambulancier
- Centre National de Convalescence Emile Mayrisch
- Transfusion sanguine
- Cours élémentaires en secourisme
- Doheem Versuergt
- Section canine

Aider

[Faire un don](#)

Contact

[Contact](#)

### Centre de transfusion sanguine

Start



Microsoft Word

Microsoft PowerPoint - ...

Croix-Rouge luxemb...



11:42 AM