
Need for a uniform European registration system for volunteer participation?

Annick Peremans
Research Centre Aalst - Belgium

Conflict of interest

No grants received from any company mentioned in this presentation

Presentation is non-commercial and the author always controlled the content of the slides

Agenda

Framing the landscape of study volunteering	Frequency
	Types
	Location

Current available info

Observations on
registration and registers

Proposal going forward

Frequency of Volunteering

Guidelines for Phase 1 Clinical trials (abpi)

Subjects
must
neither:

Take part > one trial at a time

Receive > 10 milliSievert of radioactivity
in any 12-month period

In general, subjects should not receive
an IMP systemically < 3 months after
the previous one

Studies with Healthy Volunteers

Types

Phase I studies

Phase II studies with healthy volunteers as comparator

Vaccination studies

Device studies

Studies with a diet

Investigator driven studies (academia)

Observational studies

Volunteer temptations

Why
participate?

Payment

Travel reimbursement

Internet information: where,
payment, use of database(s)

Where?

Where

Phase 1 units

Hospital departments

Vaccination centres

Number of participating Healthy Volunteers

01/01/2012 till 31/12/2012

2012 Europe

Clinicaltrials.gov: 317 studies

2012 Belgium Phase I

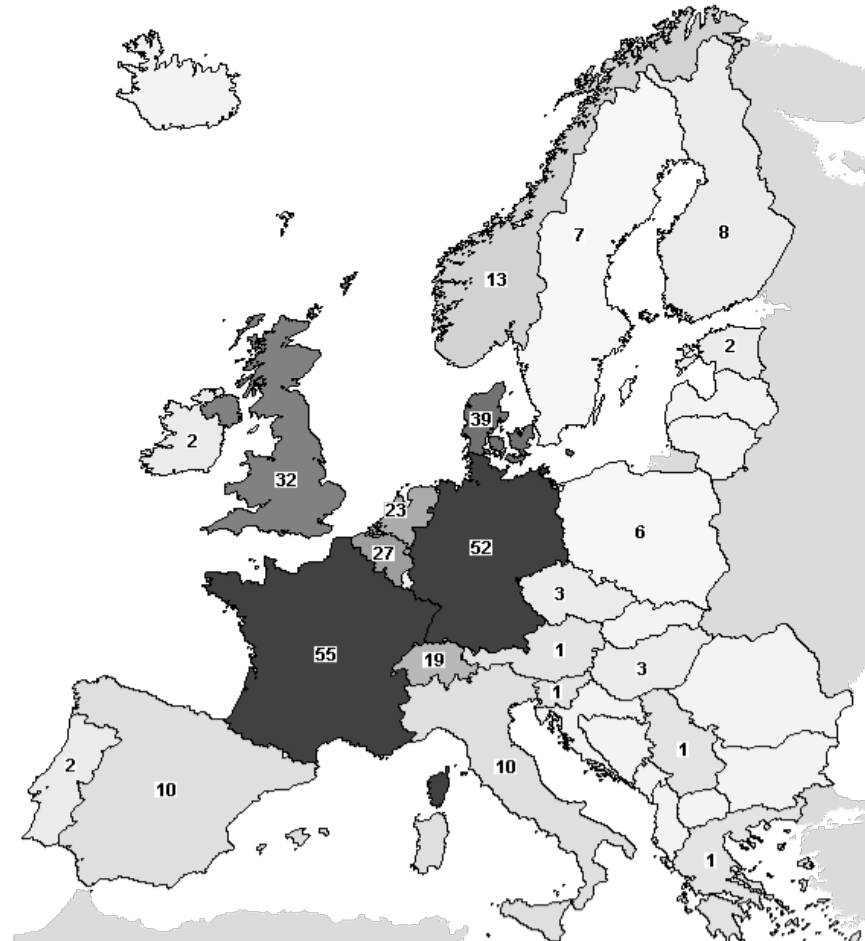
Clinicaltrials.gov: 27 studies



Clinicaltrials.gov: underestimation

Number Healthy volunteers: > 6.340 / year

(Belgium 2012: 2.457 included subjects)



Available information

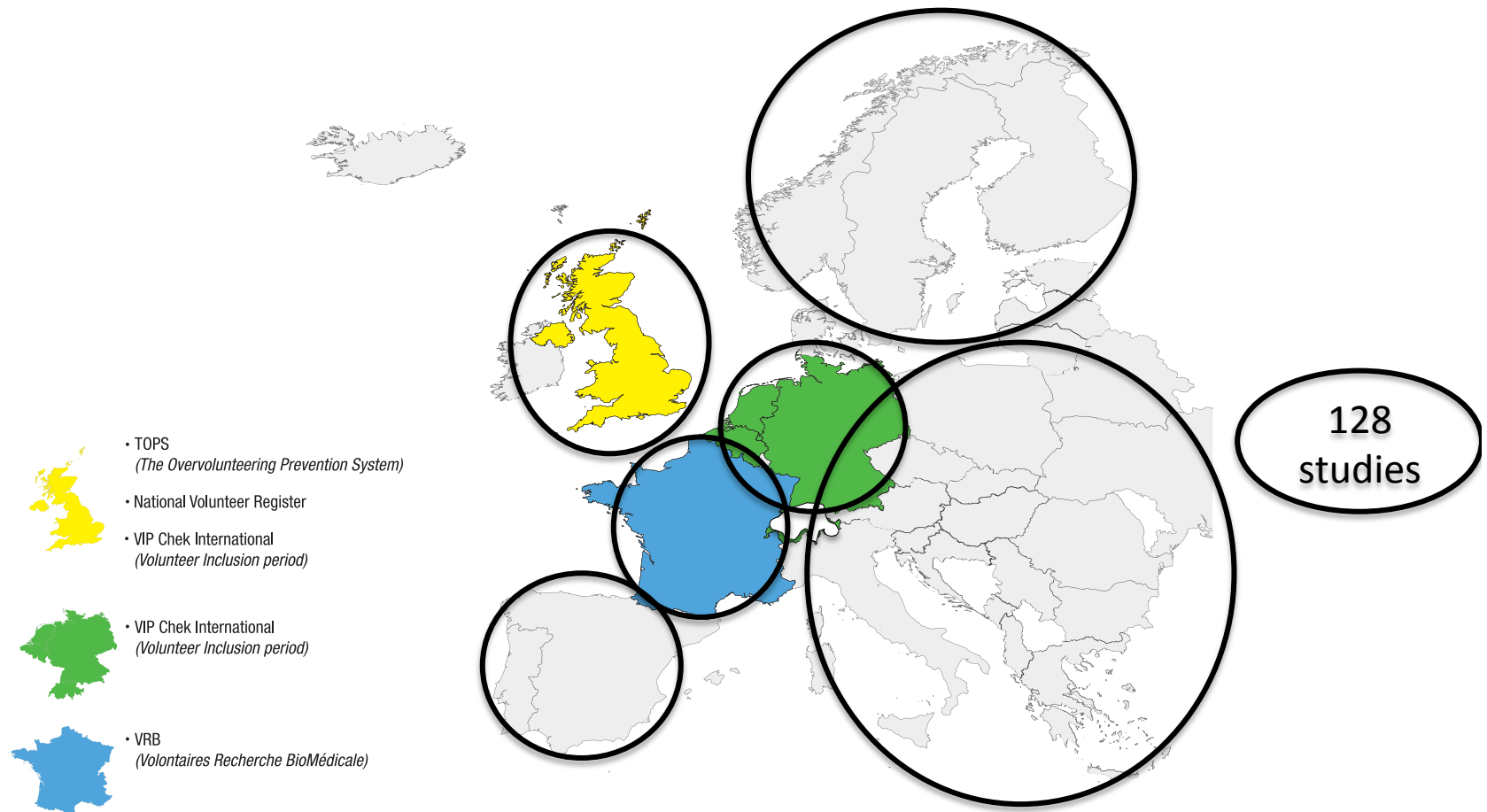
Conclusion:

Ambiguity in information

Number of studies with healthy
volunteers

Number of healthy volunteers
participating

Central Register Databases in Europe



France

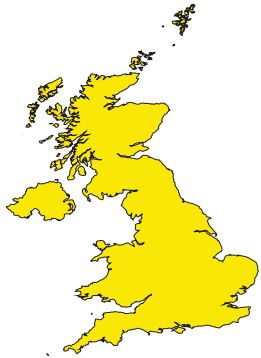


VRB (Volontaires pour la Recherche BioMédicale)

- Database French Ministry of Health
- Web-based

<i>Positive</i>	Free Mandatory use (Loi Huriet 1988) Social security number + initials Used for all subjects receiving a compensation
<i>Negative</i>	Travelling French volunteer

UK

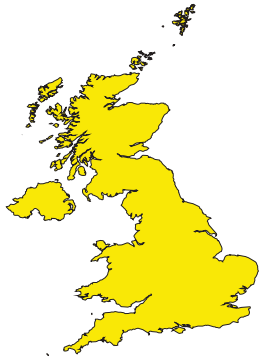


TOPs (The Overvolunteering Prevention System)

- Privately owned Trust
- Web-based
- Not mandatory – MHRA accreditation

<i>Positive</i>	Free 55 Research Units (All commercial units and many non-commercial)
<i>Negative</i>	Volunteer identification UK citizen: Insurance number Foreigners: Passport number and nationality Only used in UK

UK



National Volunteer Register

- Privately run, Web-based
- Open access database of Richmond Pharmacology
- Used by 8 UK sites

<i>Positive</i>	Free Subject identification Photographic ID (Full name & Date of birth)
<i>Negative</i>	Only information of 1 CRO

Belgium, Germany, The Netherlands

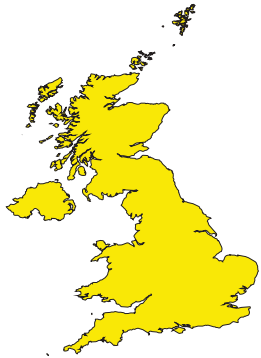


VIP (Volunteer Inclusion Period) check international

- Privately owned
- Windows – based software application

<i>Positive</i>	Subject identification Photographic ID (full name, date of birth, sex, nationality) Date last follow-up Certificate endorsing participation
<i>Negative</i>	Payment Time consuming Not used by all commercial units Not used by hospitals & vaccination centres Future of VIP check?

UK



VIP check (Volunteer Inclusion Period)

- used by one site for bridging studies

Bridging Studies

Bridging studies:

They evaluate the influence of ethnic factors

Efficacy and daily doses are typically lower in Asia than in either the United States or the European Union

Recruitment of Asian volunteers in UK, Germany and France

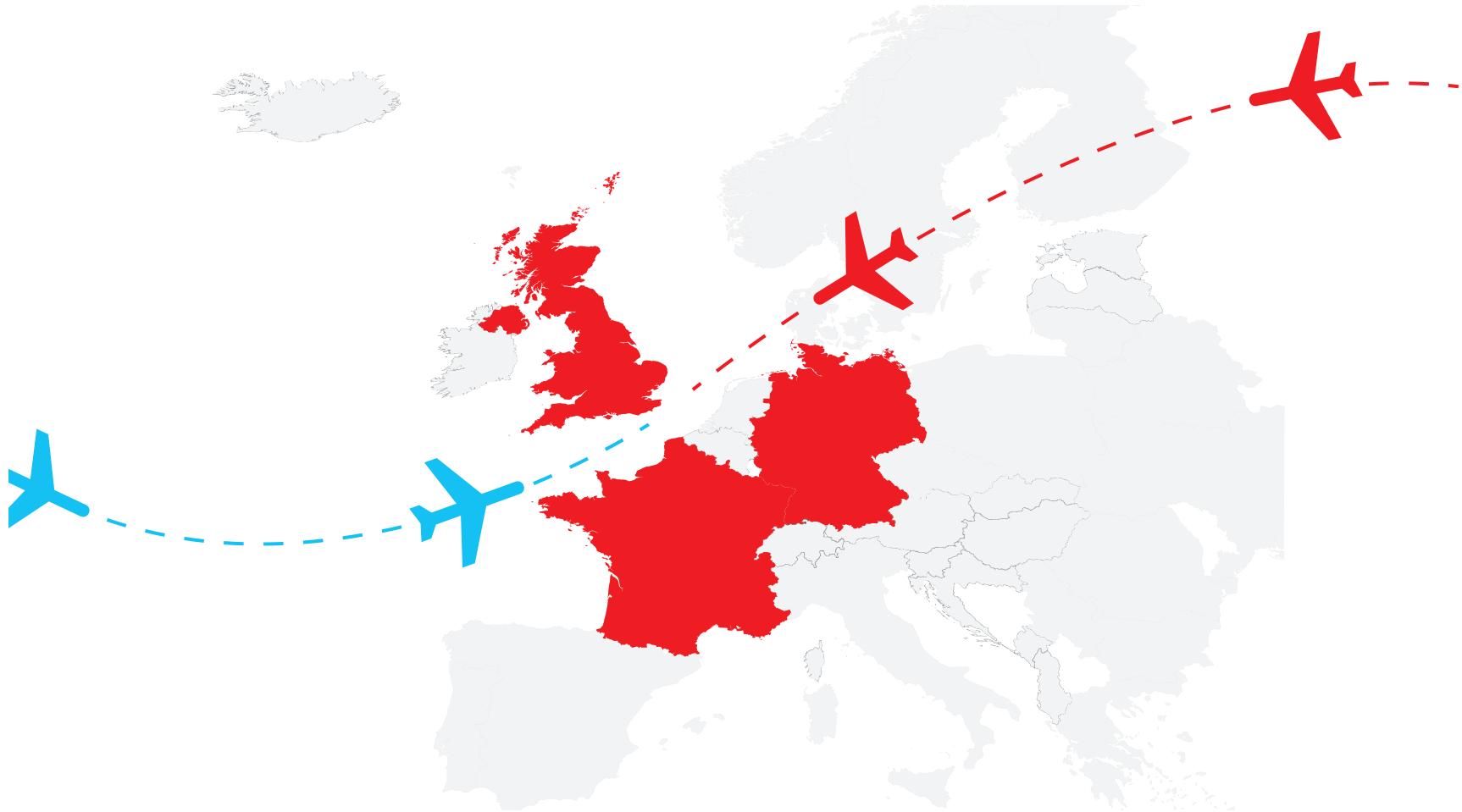
Bridging Studies

Inclusion criteria: First generation (Asian parents and grandparents)

Born in Asia, Asian passport

Living outside of Asia for less than 5 years

Bridging Studies



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Survey VIP check detection

Small Survey: 7 Belgian Phase 1 units (3 months)

1.475 subjects checked

6 not eligible subjects

6 false positive subjects

PSSS

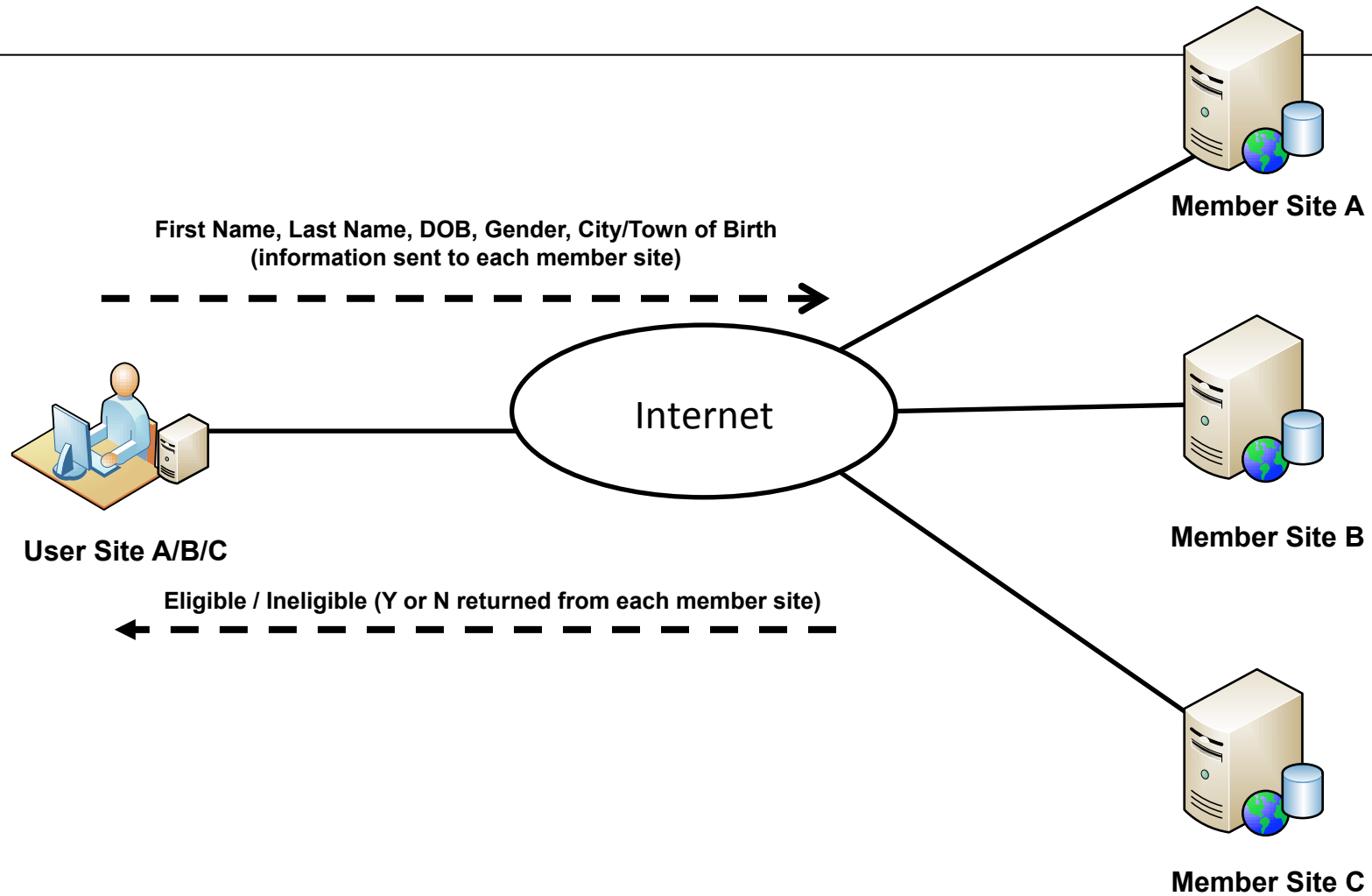
PSSS

Testing phase of Perfect Search Spider System

Importing volunteer records from an excel file into the local PSSS query database (data remains in your control)

Close network system

PSSS: How does it work?






PSSS: Status Quo



Site	Location	Phase
RPL	UK	Testing
Parexel	UK	Testing
CHDR	Netherlands	Testing
PRA	Netherlands	Testing
QPS	Netherlands	Testing
CRS (2 sites)	Germany	Testing
OLV	Belgium	Testing
ICON	UK	Set Up
MEU	UK	Set Up
Covance	UK	Final Review
J&J Ph I	Belgium	Set Up
Pfizer Ph I	Belgium	Set Up
Gent	Belgium	Set Up

PSSS: Next Steps

- Bring on line further B test sites -31/01/2013 
- 1 month of further testing - 28/02/2013 
- Suggested updates agreed, programmed & tested - 22/03/2013 
- System Validation - 05/04/2013
- Roll out across sites in UK and mainland Europe - 01/05/2013 onwards
- HRA: Presentation of PSSS to Phase I advisory working group (UK) - May 2013??

PSSS

PSSS (Perfect Search Spider System)

<i>Positive</i>	Subject identification: Photographic ID Easy & fast to use (import of excel sheet) Date last follow-up Certificate endorsing participation No storage of data
<i>Negative</i>	Payment
<i>Current problems</i>	Concerns about confidentiality Problems installation Slow reaction of testing facilities ? What about France ?
<i>Interested?</i>	k.berelowitz@richmondpharmacology.com

Central Register Databases in Europe

Conclusion:

French people need to stay in France

No waterproof system in
UK, Germany, The Netherlands, Belgium

Existing systems not used by all institutions

No system in other European countries

They do not prevent simultaneous and multi
participation

Ethical, Legal & Medical Considerations

Considerations:

Possibility of unknown interactions

Possibility of contaminated study parameters

Uncontrolled radiation exposure

Unknown consequences for the research subjects

Loss of insurance coverage due to breach of warranty for research subjects

Overall Conclusion

Conclusion:

Need for European regulation and legislation on participation of Healthy Volunteers in all types of clinical trials in Europe

Need for central European Subject Database

Raise the ethical standards and safety of clinical research in Europe to a higher level

Global European Subject Database

Conditions: Mandatory for all institutions in Europe including healthy volunteers

Unique subject identifier (finger print? Iris scan?)

Web-based

Dealing with language specific characters

Proof of verification (reports) – review by Pharmaceutical Companies

Global European Subject Database

Conditions: Standardized procedures

User friendly and not time consuming

Confidentiality

Free?

Also patients?

Current Situation

May
2011

European platform on early phase (AHPPI, AGAH, CLUB Phase I, BAPU) requested a pan European approach for registration of healthy volunteers to EU & Belgian Authorities

Active lobbying ...

QUESTIONS AND ANSWERS

Annick Peremans