Federal agency for medicines and health products

The Clinical Trial Regulation : State of play at EU and National level

Greet Musch

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Agenda

- Strategic view and position FAMHP
- CTR aims and CTR at EU level
- National implementation of the CTR workprocess
- Additional initiatives at national level
  - Accreditation of Phase 1 Centres
  - Database for healthy volunteers

1. Strategic view (1)

- **Famhp active partner in the EU strategy:**
  - Expert Group on clinical trials (Eu Com)
  - Clinical Trial Facilitation Group (HMA)
  - EU Portal and database working groups
  - GCP inspectors working party
  - EU – Network training centre :
    - Curriculum for clinical trials
    - Training on FIM guidance

- **Famhp designated as national contact point in CTR**

- **Famhp selected Early Phase Development as one of its Centres of excellence**

- **Clinical trials as part of access to innovation**
  Liaison with EU SAWP and EU network of National innovation offices

1. Strategic view (2)

Planned initiatives:

- Incentive : 0 € fee for handling of initial applications and substantial amendments ;
- Accreditation of phase 1 centers on voluntary basis
- National data base for healthy volunteers
- Info to patients and healthcare providers for clinical trials running in Belgium
- Campaign creating awareness towards the citizens and general practitioners (launch November 2017)
- Patient centricity

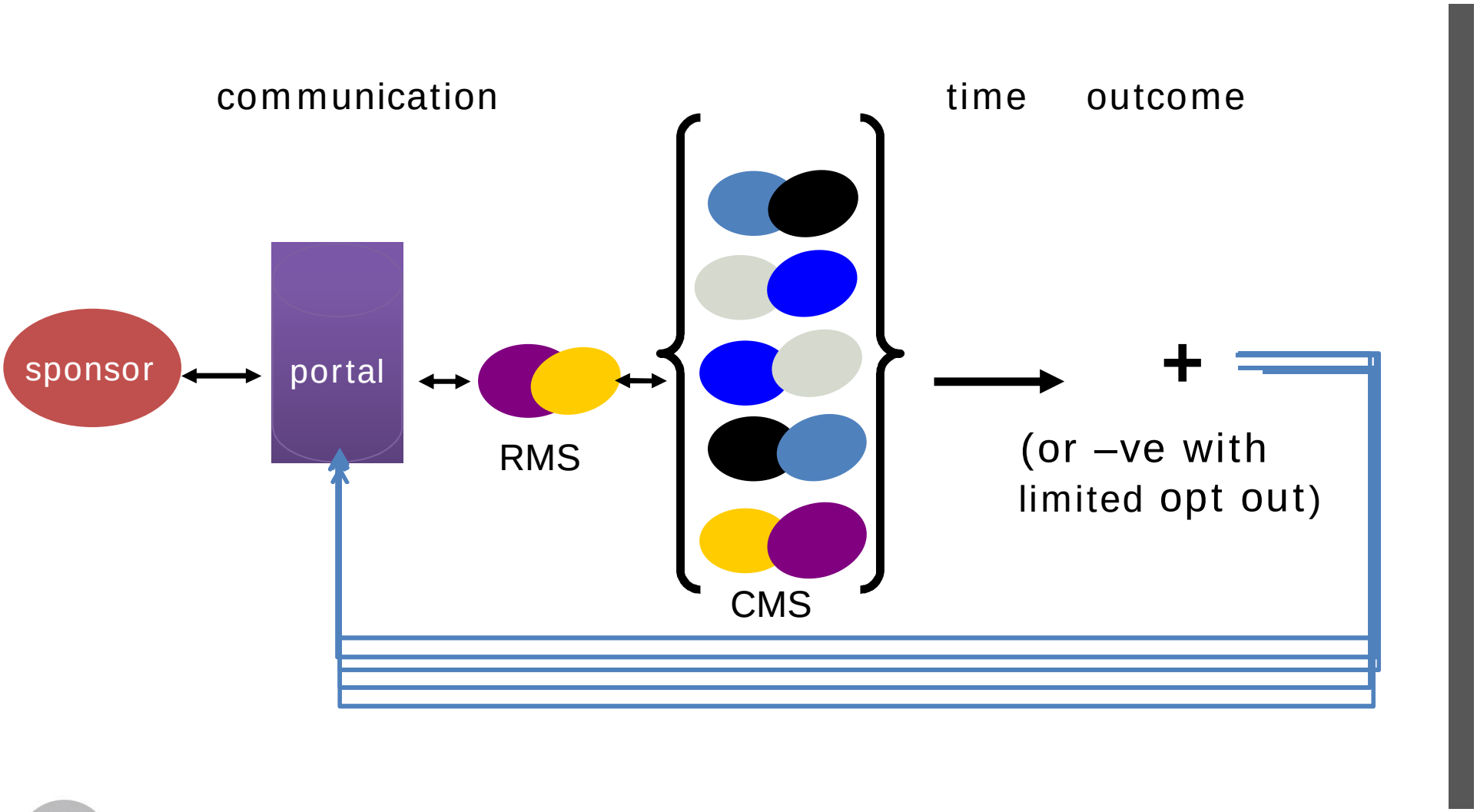
2: The EU clinical trial regulation : benefits for the patient

- **Increased efficiency avoiding unnecessary duplication / repetition of unsuccesfull trials**
  - Involvement of patient representatives in the evaluation process : anticipated B/R is positive and permanently monitored

- **Highest standards of safety**
  - GCP
  - Safety
- **Increased Transparancy**

- **Specific attention to the protection of participants**
  - ICF and subject's rights
  - Damage compensation
  - Vulnerable populations (incapacitated subjects/minors; pregnant /breastfeeding women , emergency situations ..)

2. CTR: New simplified procedure in EU



2. CTR: New simplified procedure in EU

- Harmonisation in Europe regarding requirements, timelines, approvals likely easier recruitments

- Centralisation in Europe at sponsors – especially for multi-national trials

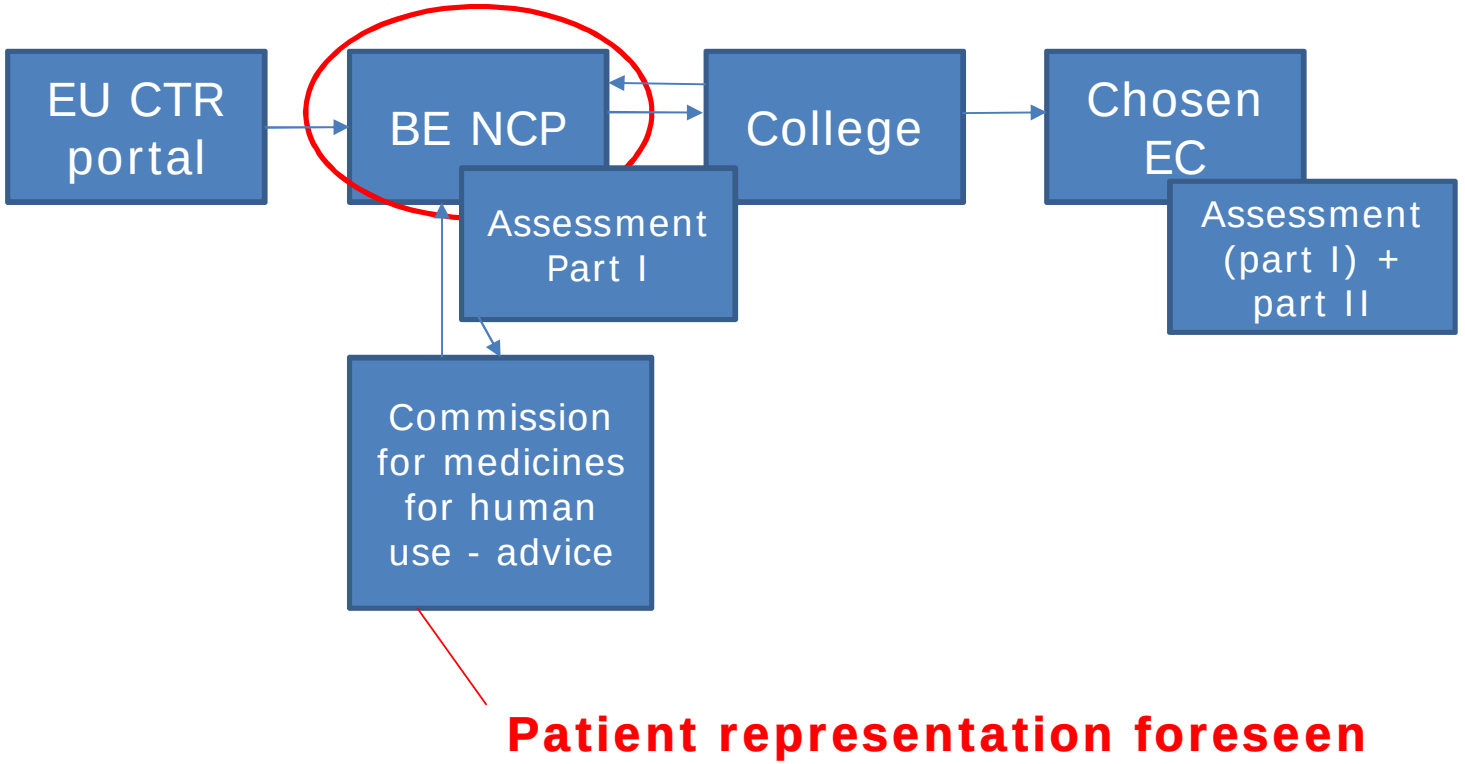
- More transparency in Europe (protocol, financial agreement, investigator CV published, investigators DOI published in BE, redacted assessment reported published, redacted study report published), IMDP will not be published.
  Leading to less unnecessary exposure of participants/patients .

2. Planning CTR in EU

- CTR expected to go live in 2019.

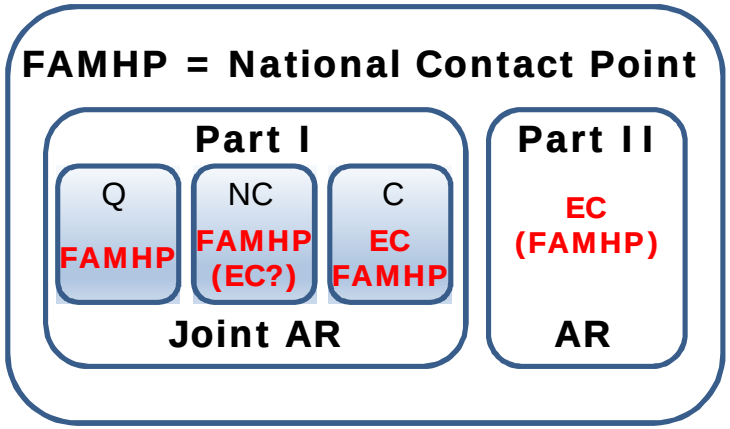
3. Belgium: processes and workflow

1. The FAMHP as national contact point (NCP)



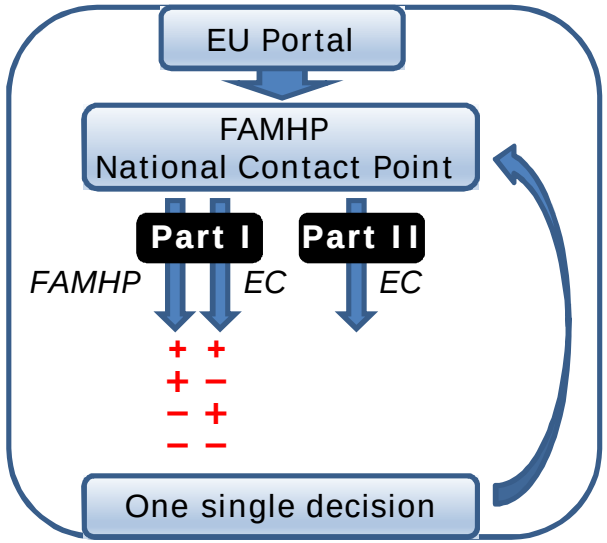
3. Belgium: processes and workflow

AR Part I:	**Quality:**	**FAMHP**
	Non-Clinical:	**FAMHP (EC?)**
	Clinical:	**EC and FAMHP**
AR Part II:		**EC (FAMHP)**



3. Belgium: processes and workflow

2. The “College” at the FPS of Public Health in a one-to-one relationship with the FAMHP



3. Independent ethical evaluation (independent from the trial site)
4. Representation of lay-men and patients
5. Added value of co-assessment (in touch with medical reality)
6. Short timelines for phase 1 trials will be maintained
7. Pilot joint assessment FAMHP-EC ongoing

3. Belgium: processes and workflow

- Agency: peer review, also sections to be evaluated which were not evaluated before (as clinical), more interchange with evaluating EC

- Reduced number of EC's in Belgium, stricter procedures, quality system, use of templates. Large hospitals with large EC's – will lead to smaller EC's and some middle size hospitals with an EC will have a larger EC – on the longer term.

To prepare us –> CTR Pilot

4. Accreditation of phase 1 centres : Why ?

Uncertainty is inherent to first in human trials and other early phase trials and therefor these require:

- experience and training of staff
- preparedness for emergencies at the site and a nearby hospital
- equipment and procedures
- (see section 8.4 of EMEA/CHMP/SWP/28367/07 Rev. 1)

The Law of 7 May 2017 foresees the possibility for centres that conduct such trials to become accredited on a voluntary basis

4. Accreditation of phase 1 centres : Why ?

Advantages:

- Authorities approving clinical trials know that these centres adhere to the rules set in the Royal Decree

- Participants to the clinical trial know that these centres are using the best possible standards and are prepared to handle emergencies if these would occur despite precautions taken

- The centre can prove to Sponsors that it adheres to harmonised standards

4. Accreditation of Phase 1 Centres : Implementation

Retribution 16.996 Euro

A Royal Decree is being prepared after extensive discussion with stakeholders

Aim to start as early as possible in 2018

Primarily for centres that recruit healthy volunteers, but since it is voluntary it is open to any centre that conducts early phase clinical trials

5. Database for healthy volunteers

Healthy volunteers are compensated for the inconvenience that may be caused by participation to a clinical trial

Therefore they may be tempted to enroll in too many trials in too short time

Healthy volunteers have usually nothing else to gain personally from participating a clinical trial than the recompensation, but are exposed to low but inherent risk

Healthy volunteers should be able to recover from procedures (e.g. blood draws) and potential effects from study drugs

5. Database for healthy volunteers

Therefore participation of healthy volunteers in any clinical trial on Belgian territory should be recorded to prevent over-volunteering

Such a database should be simple, web based, maintained by an independent instance

It would be preferable that data can be transferred to a European database if this would be developped in the future

5. Database for healthy volunteers

Will be proposed to become mandatory for all centres that recruit healthy volunteers in clinical trials, whatever the stage of development

Will be an integral part of the voluntary accreditation for phase I centres

Feasibility excercise has been finalised

Use of simple means of identification or use of biometrics were considered

If biometrics are to be used, it should be assured upfront that legislation on privacy is respected

6. Additional initiatives at national level :

- **Info to patients and health care providers on running clinical trials in Belgium at famhp website**
- **Accreditation of phase 1 centres and national Dbase for healthy volunteers**
- **Awareness raising (campaign oriented towards participants and treating physicians)**
- **Patient representation before and during the assessment of clinical trials**
- **Facilitating recruitment of patients**
  - Cooperation between centres (i.e. paediatric oncology)
  - Enhancing and facilitating the role of the general practicioner
- **Fostering the coöperation of all the concerned stakeholders in order to facilitate the access to innovation in the benefit of the patient .**

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Thank you for listening

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