Report

Clinical Patient Management System meeting

14 January 2019
University Medical Center Groningen (UMCG)
Groningen, The Netherlands

Objectives:

1. To familiarize a group of MetabERN-members representing an EU-member state in MetabERN with the CPMS;
2. To exchange views on CPMS between different stakeholders, based on experiences, survey outcomes, lessons-learnt, steps-to-take and potential future functionalities, in particular for MetabERN.

Preparation:

The **expectations of the participants** before the meeting were the following:

- Knowledge transfer would take place;
- Second opinions on patient cases would be improved and validated;
- CPMS is a secure communication channel;
- Discussion on barriers to working with the system.

In preparation, we circulated a Survey Monkey questionnaire amongst MetabERN HCPs in December. The survey results are available after the closing date.

List of Invitees and Participants: see Annex I

Program:

Time	Topic
9.00-9.10	**Welcome and introduction** *Corine van Lingen (Stakeholder Manager MetabERN) & Terry Derks (UMCG, WP-5 leader)*
9.10-9.45	**Background and legal framework of CPMS** *Christophe Kusendila, Policy Assistant, Unit B.3, European Reference Networks and Digital Health, European Commission*
9.45-10.00	**Discussion and questions** *Moderators: Corine and Terry*
10.15-10.45	**MetabERN experiences with CPMS** *Moderator: Terry Derks* Based on MetabERN-survey result, feedback from country representatives, patients and HCPs focusing on the 3 main issues: * Informed consent * CPMS and barriers for use: from log-in to panels * IT & Data security issues (GDPR)
10.45-11.15	**State of Play of CPMS** *Caroline Pacquier (Project Manager CPMS/European Commission) will be present via video-link*
11.15-12.00	**Interactive Session CPMS** *Corine van Lingen* *Caroline Pacquier (Project Manager CPMS/European Commission)*

	How to enrol a patient and start a panel + Q&A of technical questions
13.00-14.00	**Break-out sessions** • Needs from different stakeholders - • Break-out in smaller groups and come up with concrete suggestions • European Commission (EC) • MetabERN • Patient Representatives • HCPs (IT-department, Privacy officers)
14.00-14.45	**Lessons learnt and bringing together steps-to-take** *Moderators: Corine and Terry* • Feedback from each group • Bringing together of all the actions points and distribute them amongst participants –Steps to take
15.45-16.30	**Future functionalities of CPMS**: what do we need to be featured in the system in the future to improve the use

The meeting had an **interactive characte**r and the participants took the opportunity to discuss and interact with each other about CPMS. The most important outcomes of the meeting are listed below including the steps-to-take that are linked to them.

Main outcomes and steps-to-take

1. Main barriers for the use of CPMS

In the meeting and as outcome of the CPMS survey that the Coordination Office sent out before the meeting to all its members, it became clear that there are multiple barriers for not using the CPMS:

a) A lack of time to enrol a patient and upload data (more staff is needed);

b) Technical issues, such as:

- A firewall in the hospital;
- A lack of know-how on how to use the system (despite the access to log-in procedures and tutorials);
- Lack of interoperability with electronic records in hospitals

c. Legal issues related to data protection, security and privacy;

d. Issues related to Informed consent form (ICF).

These barriers need to be addressed in order to enhance the use of the system within MetabERN. The grant that MetabERN receives this year will enable us to hire support staff that can be instrumental in helping HCPs in their first steps to use the CPMS. Participants ask for local support at HCP level. Member States need to be reminded that they need to provide support to ERN-members.

- Steps-to-take*:* the Coordination office will share the results of this meeting and the CPMS survey with the relevant units of the EC.
- Recommendation*:* To appoint panel managers as a new role in CPMS who can upload the information of the panels. *Post-meeting information: The panel manager role will be released in CPMS ver.17 beginning of March 2019.*

2. Informed Consent form

Some of the participants raised concerns about the content of the *informed consent form* (ICF) stating that the formulation of the form needs to be changed to better reflect data safety and patient interests.

The second consent box on the ICF states that 'de-identified data can be included in an ERN database or registry': some participants felt that it is unclear which database or registry is meant with this.
The EC representative explained that the CPMS itself is a database and also contains a registry in which patient data is being stored. The link with a ERN-dedicated registry (such as the UIMD) needs to be clarified by the persons running the UIMD project (Stefan Kolker). If an ERN decides to link the CPMS to a registry the data of the patient can possibly be stored in that registry as well.

Some participants felt that the third consent box on the form stating that a patient 'would like to be contacted about research' was ambiguous since there is also a research function in the CPMS. The general consensus was that a patient could not be included in research of which the purpose and details are not explained to him/her before starting this research. There was a general feeling that the use of the term 'Research' within the CPMS was perhaps not very clear (see point 4). The EC representative reiterated that the third request for consent does not ask patients to participate in a research project. He made it clear that, when patients have agreed to be contacted for research, they will have to provide consent again for that specific research project. In addition, the EC representative noted that currently there is no decision taken yet on a specific ERN research strategy.

- Steps-to-take*: the EC representative will look into these points and report back to the relevant ERN bodies (e.g. ERN Coordinators Group, IT Advisory Group)*
- Recommendation: After translations, but before implementation, the informed consent forms require:
    1. Rewording, for which input from patients in the native languages is needed. Query might be a possible option;
    2. Modification according to national legislation. For instance, in the Netherlands separate forms are required according to the ages: < 12, 12-15 and > 16 years of age. This should be harmonized at a national level and is the responsibility of each Member State and/or national HCP to implement.

3. De-identification of patient data in the first screen of patient enrolment

Some participants expressed their concerns about the first screen in which a patient is enrolled. This screen asks for the patient name and date of birth. As soon as the HCP clicks on the button 'enrol patient' to share the data in the CPMS, this data is de-identified/pseudononymised by the CPMS and a nickname will be asked and used after this. This security step was not deemed sufficiently safe for some of the participants, who stated 'the data belong to the patients, the HCP has the responsibility to share them safely'. On this responsibility, the EC representative mentioned the currently on-going amendment of the Commission Implementing Decision 2014/287/EU which will clarify the joint responsibility of the HCPs and the Commission, as they are 'Joint Controllers' as regards the patient data in CPMS.

Furthermore, there was a question about where the personal data are stored within parts of EU-database CPMS, i.e. you cannot exclude 100% to reconnect personal data and nickname. The EC representative clarified there is no link

between the storage of data and the possibility to reconnect pseudonymised patient data to identifying data.

Two possible solutions were discussed:

1. To ask the EC to review this screen;
2. In the meanwhile, the conclusion was reached that the HCP can use de-identified data in this field as well such as a nickname or the number of his/her hospital patient registration system. In this way the HCP holds the key to de-identify and no patient data will effectively be entered into the system.

- *Steps-to-take: the EC will look into this issue and report back to the relevant bodies.*

4. The research function within CPMS

This function in CPMS is envisaged to do a query on the available data in the database. Some participants felt that the use of the term Research is ambiguous and recommended changing this into 'Queries' or 'search function'. The EC representative referred to researcher role in CPMS that can be attributed to a health professional and which allows this person to run queries (searches) on the CPMS database. This can only be done on those data where the patient has consented sharing his or her data in an ERN database or registry (second consent).

- Steps-to-take: the EC representative will look into this and report back to the relevant ERN bodies. *Post meeting information: this request for change in CPMS is registered and will be queued in DG SANTE for analysis and prioritisation.*

5. Uploading and downloading of DICOM-files

Handling of DICOM-data (MRI, CT other imaging) had been presented. During the uploading of these files an automated de-identification is implemented into CPMS. The DICOM viewer is for routine diagnostic processes but there is also the option to store DICOM files as de-identified raw data for use with the hospital DICOM viewer.

6. Patient involvement in CPMS

Some participants feel that the situation that patients do not have access to the CPMS should be rectified. In the MetabERN survey that was sent out before the meeting 61% of the 26 respondents feel that patients have the right to ask for a second opinion and hence, to talk with the expert through CPMS.
The EC representative explained that at present there is no physical access foreseen for patients in terms of their own account. It is however completely at the discretion of the treating physician to have the patient present in the room whilst he/she is attending a panel discussion.
It was concluded that in deciding to allow patients in their panel, the rights of both the HCPs and the patients should be communicated and balanced. Any future option to enable patient-participation doesn't necessarily enforce the HCP to decide otherwise, with good reasons.

- Steps-to-take: Potentially set up a pilot in which some patient cases will be discussed with the patient attending the panel in the same room as the treating physician. In principle the treating doctor can already decide on a case-by-case basis to involve, or not, the patient in his panel.

7. Participation by HPCs (and if appropriate, patients) from non-EU countries

The EC representative stated that the ERNs and the CPMS have been established under European legislation. Therefore non-EU/EEA countries would need to apply similar standards and rules (=legislation) regarding cross border healthcare and data protection, which basically is confirmed in a political agreement. As a consequence, the current consent form is also explicitly meant for patients from EU/EEA member states and accounts can only be given to EU/EEA-based healthcare providers.

8. Difficulties during emergency situations

CPMS is not set up for emergency situations in which there only a few hours available for diagnosis and treatment.

9. FAIR (Findability, Accessibility, Interoperability, Reusability) principles with regards to CPMS and the datasets generated

Suggestions for (n=10 panels) pilots:

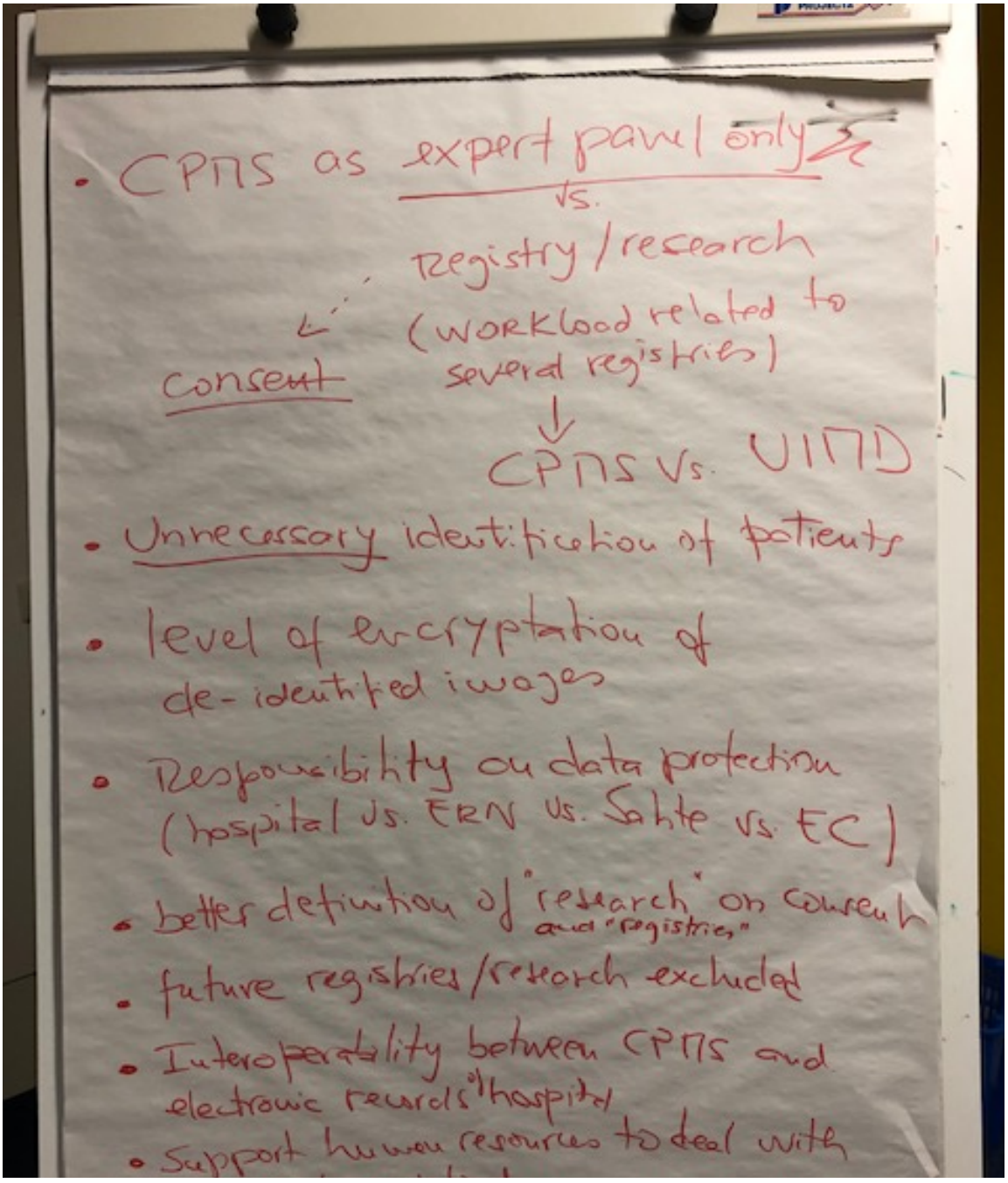
1. CPMS panels to generate standard operating procedures for expert second opinions
2. CPMS panels to generate experience with patient participation

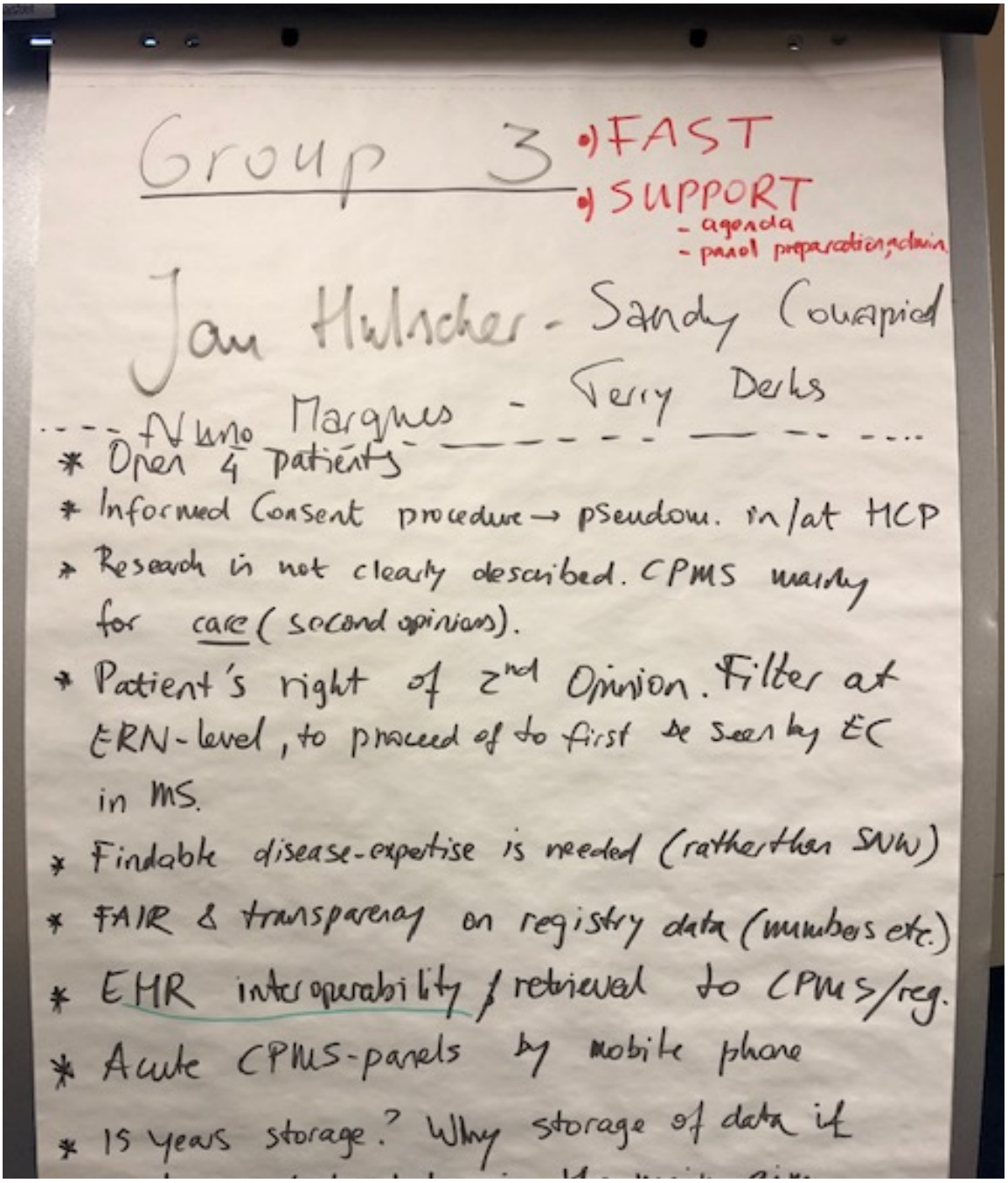
Annex I- Participants

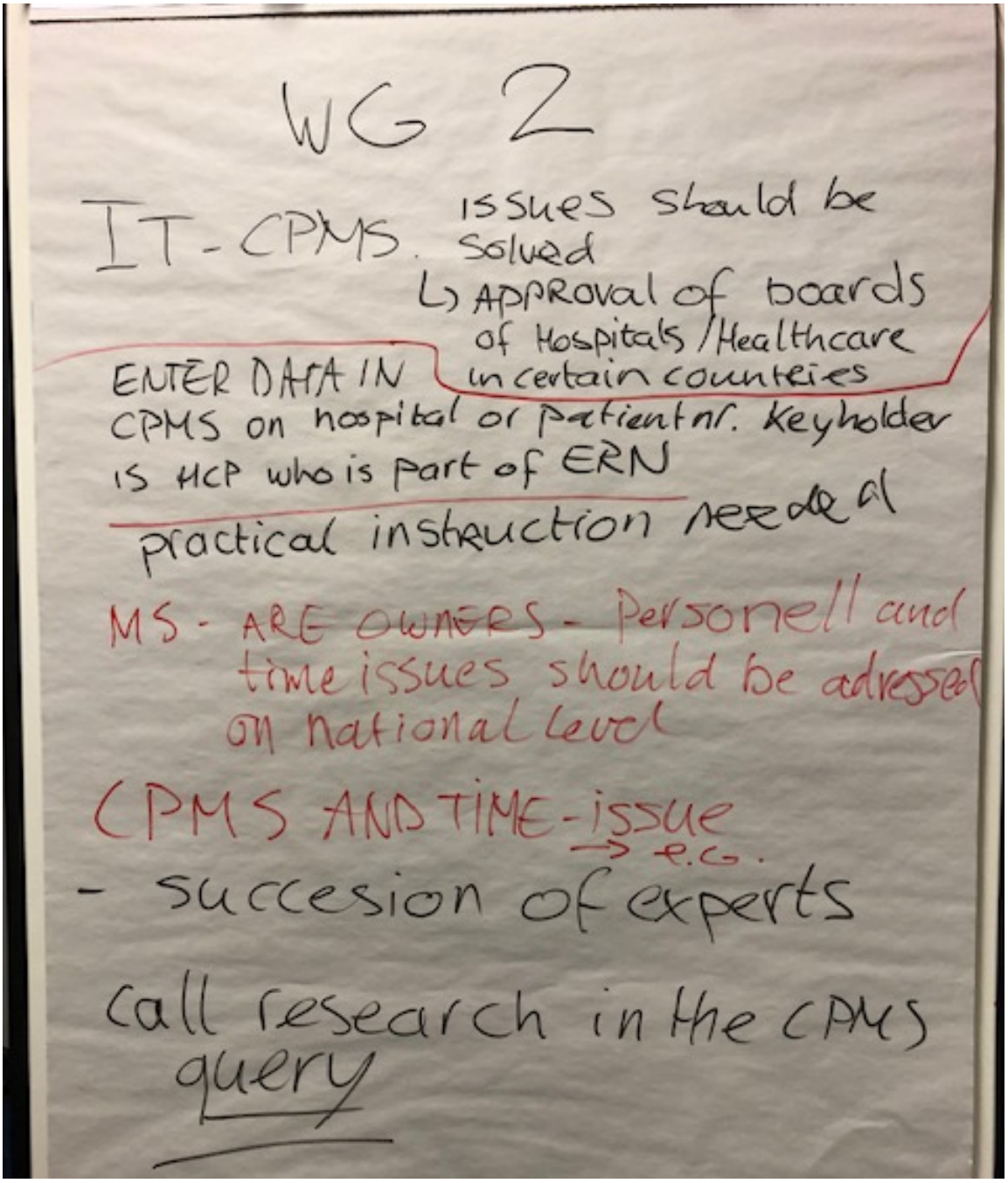
Name	Representing countries/Organisation	Representing expertise	Participated
Allan Lund	Denmark	Amino and organic acids-related disorders (AOA Subnetwork)	Yes
Terry Derks	Netherlands	Carbohydrate, fatty acid oxidation and ketone bodies disorders (C-FAO Subnetwork)	Yes
Olga Azevedo Silva	Portugal	Lysosomal Storage Disorders (LSD Subnetwork)	Yes
Niklas Darin	Sweden	Disorders of pyruvate metabolism, mitochondrial oxidative phosphorylation disorders (PM-MD)	No
Klaus Mohnike	Germany	Carbohydrate, fatty acid oxidation and ketone bodies disorders (C-FAO Subnetwork)	Yes
György Pfliegler	Hungary	Peroxisomal disorders (PD Subnetwork)	No
Dries Dobbelaere	France	Amino and organic acids-related disorders (AOA Subnetwork)	Yes
Sandy Courapied	France	Amino and organic acids-related disorders (AOA Subnetwork)	Yes
Danijela Petković Ramadža	Croatia	Lysosomal Storage Disorders (LSD Subnetwork)	Yes
Giovanni Ciana	Italy	Lysosomal Storage Disorders (LSD Subnetwork	No
Lut Debaere	Chair of the MetabERN Patient Board	Chair of the MetabERN Patient Board	Yes
Hanka Dekker	Member Steering Committee MetabERN Patient Board	Member Steering Committee MetabERN Patient Board	Yes
Nuno Marques	Member Steering Committee MetabERN Patient Board	Member Steering Committee MetabERN Patient Board	Yes
Sebastiaante Boekhorst	Patient Connect	Patient Connect	No
Christophe Kusendila	European Commission/DG Sante	European Commission/DG Sante	Yes
Marc	UMCG	Management trainee UMCG	Yes

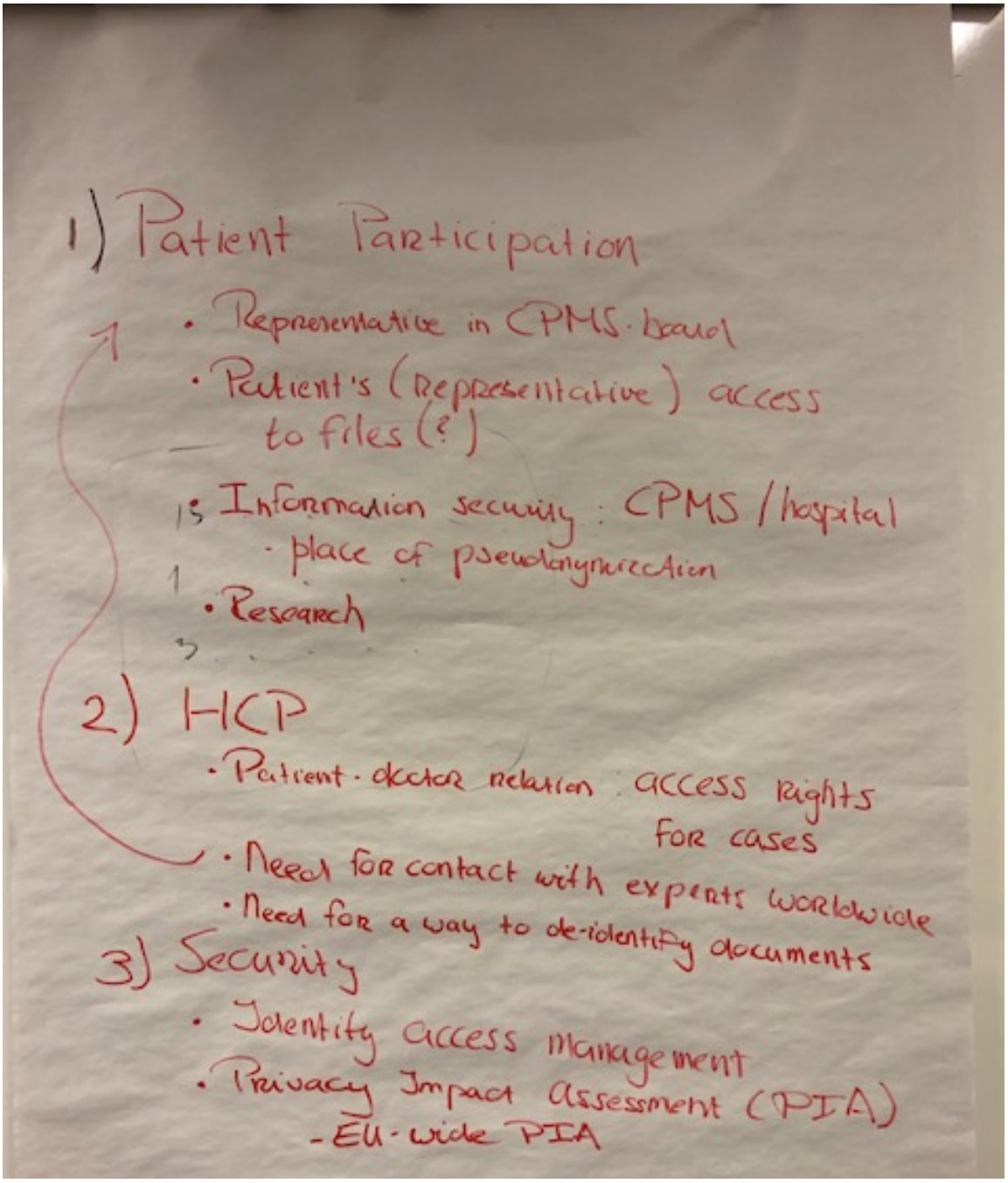
Name	Representing countries/Organisation	Representing expertise	Participated
Oosterling			
Rolf Sijmons	UMCG	Consultant clinical geneticist and professor of medical translational genetics	Yes
Jan Hulscher	UMCG	Paediatricien UMCG	Yes
Bert Moorlag	UMCG	Senior information security officer UMCG	Yes
Piet Dinjens	UMCG	Data protection officer UMCG	Yes
Corine van Lingen	MetabERN Coordination Office		Yes

Annex II- Pictures of the outcomes of the break-out sessions


• CPMS as expert panel only
vs.
Registry / research
(workload related to several registries)
consent
CPMS vs. UMD
• Unnecessary identification of patients
• level of encryptation of de-identified images
• Responsibility on data protection (hospital vs. ERN vs. State vs. EC)
• better definition of "research" on consent and "registries"
• future registries / research excluded
• Interoperability between CPMS and electronic records of hospital
• Support human resources to deal with


Group 3
• FAST
• SUPPORT
- agenda
- panel preparation, chair
Jan Hulscher - Sandy Couwenberg
Marques - Terry Derks
* Open 4 patients
* Informed Consent procedure → pseudon. in/at HCP
* Research is not clearly described. CPMS mainly for care (second opinions).
* Patient's right of 2nd Opinion. Filter at ERN-level, to proceed of to first be seen by EC in MS.
* Findable disease-expertise is needed (rather than SNW)
* FAIR & transparency on registry data (numbers etc.)
* EHR interoperability / retrieval to CPMS/reg.
* Acute CPMS-panels by mobile phone
* 15 years storage? Why storage of data if


WG 2
IT-CPMS. issues should be solved
↳ Approval of boards of Hospitals/Healthcare in certain countries
ENTER DATA IN CPMS on hospital or patient nr. Keyholder is HCP who is part of ERN
practical instruction needed
MS - ARE OWNERS - personell and time issues should be adressed on national level
CPMS AND TIME-issue → e.g.
- succesion of experts
call research in the CPMS query


1) Patient Participation
• Representative in CPMS-board
• Patient's (Representative) access to files (?)
Information security: CPMS / hospital
• place of pseudonymization
• Research
2) HCP
• Patient-doctor relation: access rights for cases
• Need for contact with experts worldwide
• Need for a way to de-identify documents
3) Security
• Identity access management
• Privacy Impact Assessment (PIA)
- EU-wide PIA