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National Board of Health

The New Clinical Trial Regulation

Needs for IT support in our NCA due to the Clinical Trial Regulation and the single portal

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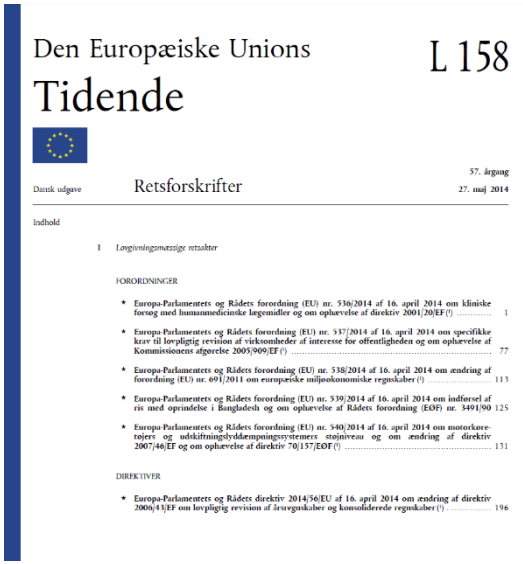
Content

- Current set-up in Denmark
- Mapping of the process according to the regulation
- Considerations on requirements to the national IT support



Den Europæiske Unions
Tidende

L 158

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Indhold

I *Lovgivningsmæssige retsakter*

FORORDNINGER

* Europa-Parlamentets og Rådets forordning (EU) nr. 536/2014 af 16. april 2014 om kliniske forsøg med humanmedicinske lægemidler og om ophævelse af direktiv 2001/20/EF (1) 1

* Europa-Parlamentets og Rådets forordning (EU) nr. 537/2014 af 16. april 2014 om specifikke krav til lovpligtig revision af virksomheder af interesse for offentligheden og om ophævelse af Kommissionens afgørelse 2005/909/EF (1) 77

* Europa-Parlamentets og Rådets forordning (EU) nr. 538/2014 af 16. april 2014 om ændring af forordning (EU) nr. 691/2011 om europæiske miljøøkonomiske regnskaber (1) 113

* Europa-Parlamentets og Rådets forordning (EU) nr. 539/2014 af 16. april 2014 om indførsel af ris med oprindelse i Bangladesh og om ophævelse af Rådets forordning (EØF) nr. 549/90 125

* Europa-Parlamentets og Rådets forordning (EU) nr. 540/2014 af 16. april 2014 om motorkøretøjers og udskiftningsdæmpningssystemers støjniveau og om ændring af direktiv 2007/46/EF og om ophævelse af direktiv 70/157/EØF (1) 131

DIREKTIVER

* Europa-Parlamentets og Rådets direktiv 2014/56/EU af 16. april 2014 om ændring af direktiv 2006/43/EF om lovpligtig revision af årsregnskaber og konsoliderede regnskaber (1) 196

Current set-up and experience

- All clinical trials with medicinal products should obtain permission from both Danish Health and Medicines Authority (DHMA) and an ethical committee (EC)
- Timelines for assessment are comparable for most trials
- The assessment is independent - decisions are shared but not coordinated
- DHMA has experience with VHP – EC does not.

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DEN NATIONALE VIDENSKABSETISKE KOMITÉ
The National Committee on Health Research Ethics

The Ethical Committees (EC)

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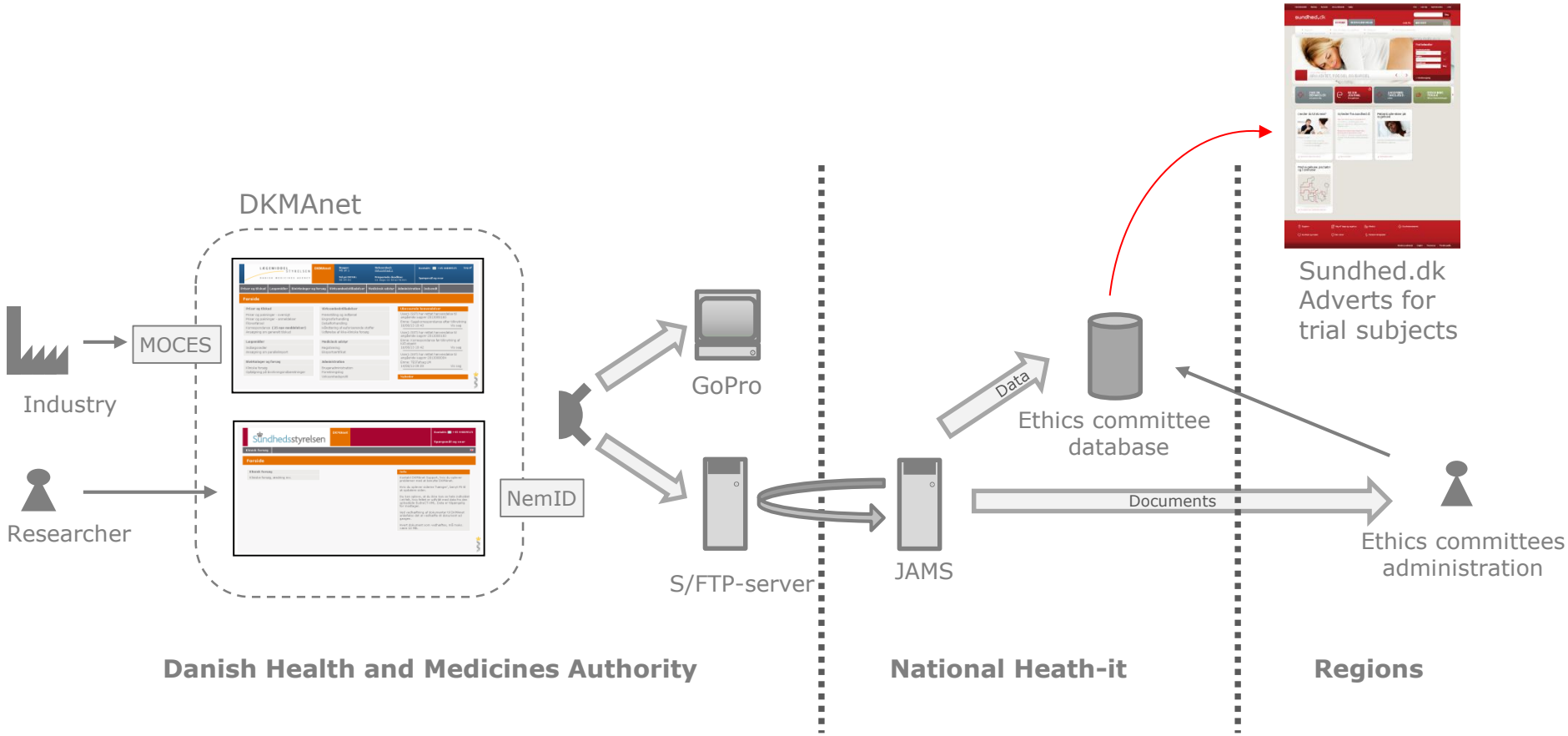
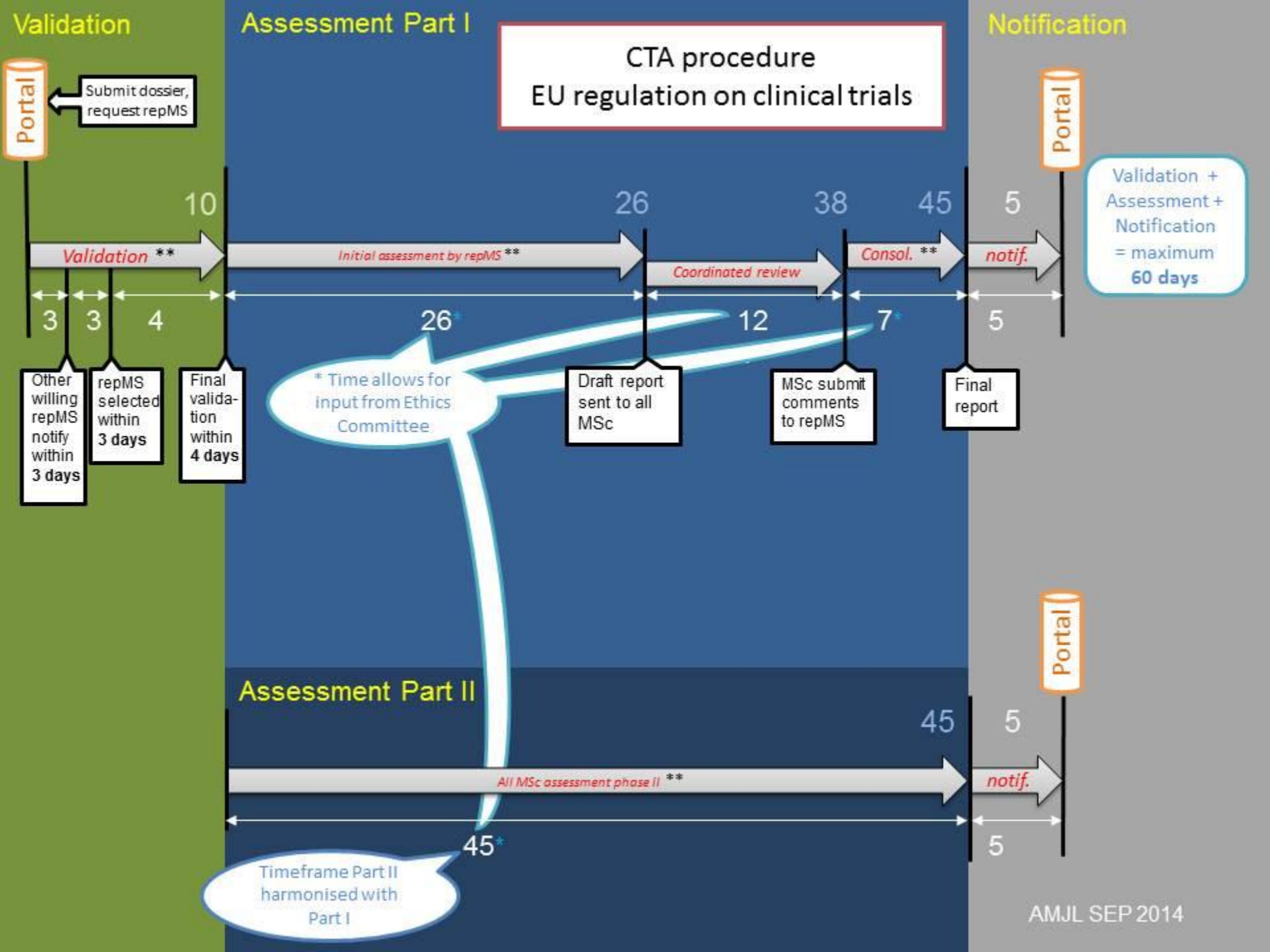
DKMAnet portal for clinical trials submissions for DHMA and EC on a voluntary basis



Volumes (DHMA data)

- App. 300 new trials each year
  - App. 200 trials expected to be multinational (RMS or CMS)
  - App. 100 trials expected to be national (RMS)
  - 180 trials from commercial sponsors
  - 120 trials from non-commercial sponsors
- Substantial number of additional submissions
  - App. 700 amendments each year
  - App. 1500-2000 additional submissions (safety reports, SUSAR, notifications)
- Volumes will increase – part I and part II submissions apart


Validation
Assessment Part I
Notification
CTA procedure
EU regulation on clinical trials
Portal
Submit dossier, request repMS
10
26
38
45
5
Validation **
Initial assessment by repMS **
Coordinated review
Consol. **
notif.
Portal
Validation + Assessment + Notification = maximum 60 days
3
3
4
26*
12
7*
5
Other willing repMS notify within 3 days
repMS selected within 3 days
Final validation within 4 days
* Time allows for input from Ethics Committee
Draft report sent to all MSc
MSc submit comments to repMS
Final report
Assessment Part II
45
5
All MSc assessment phase II **
notif.
Portal
45*
5
Timeframe Part II harmonised with Part I
AMJL SEP 2014

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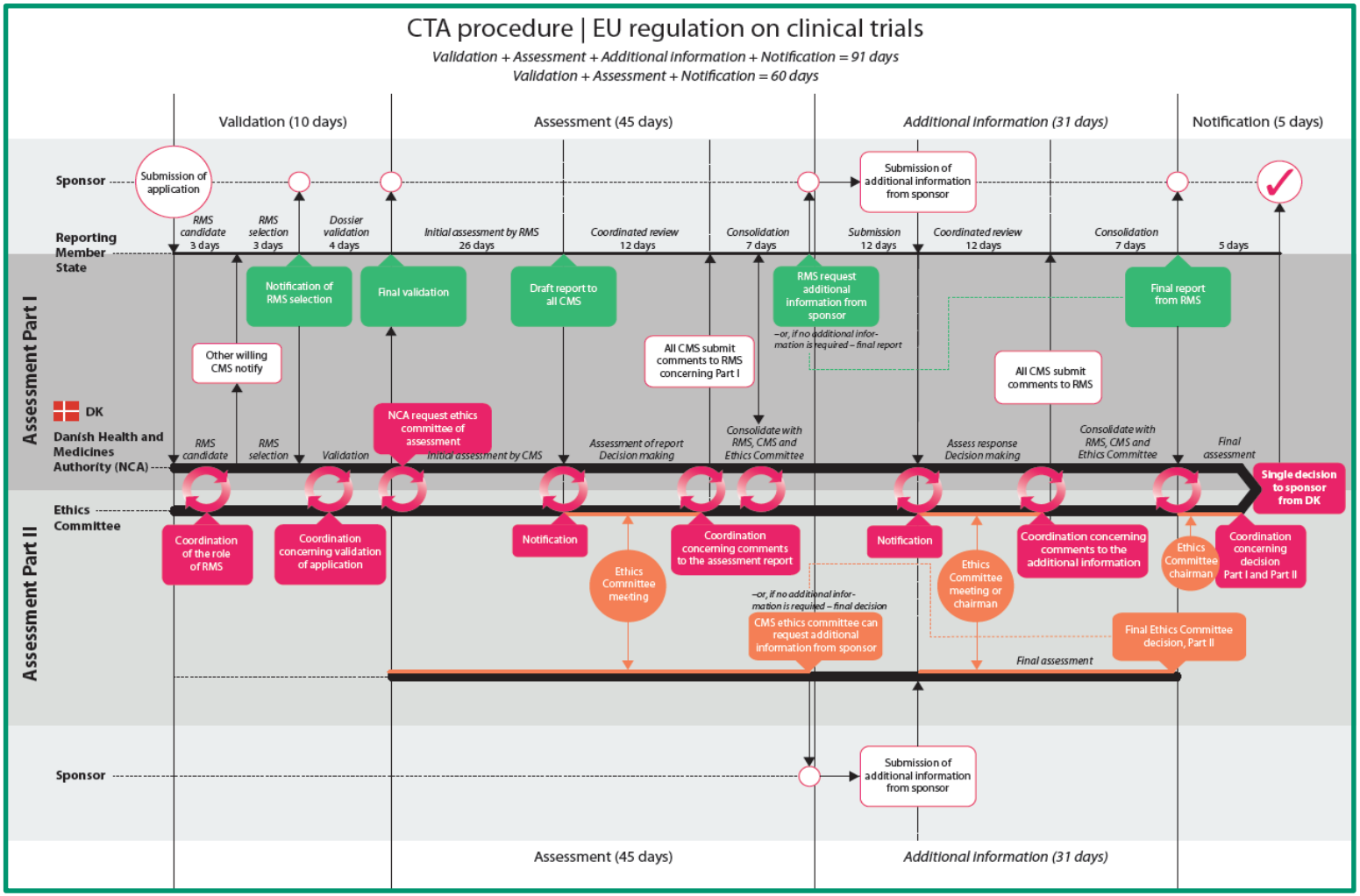
Procedure envisaged in Denmark



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Clinical Trial Applications

National coordination DHMA and Ethics

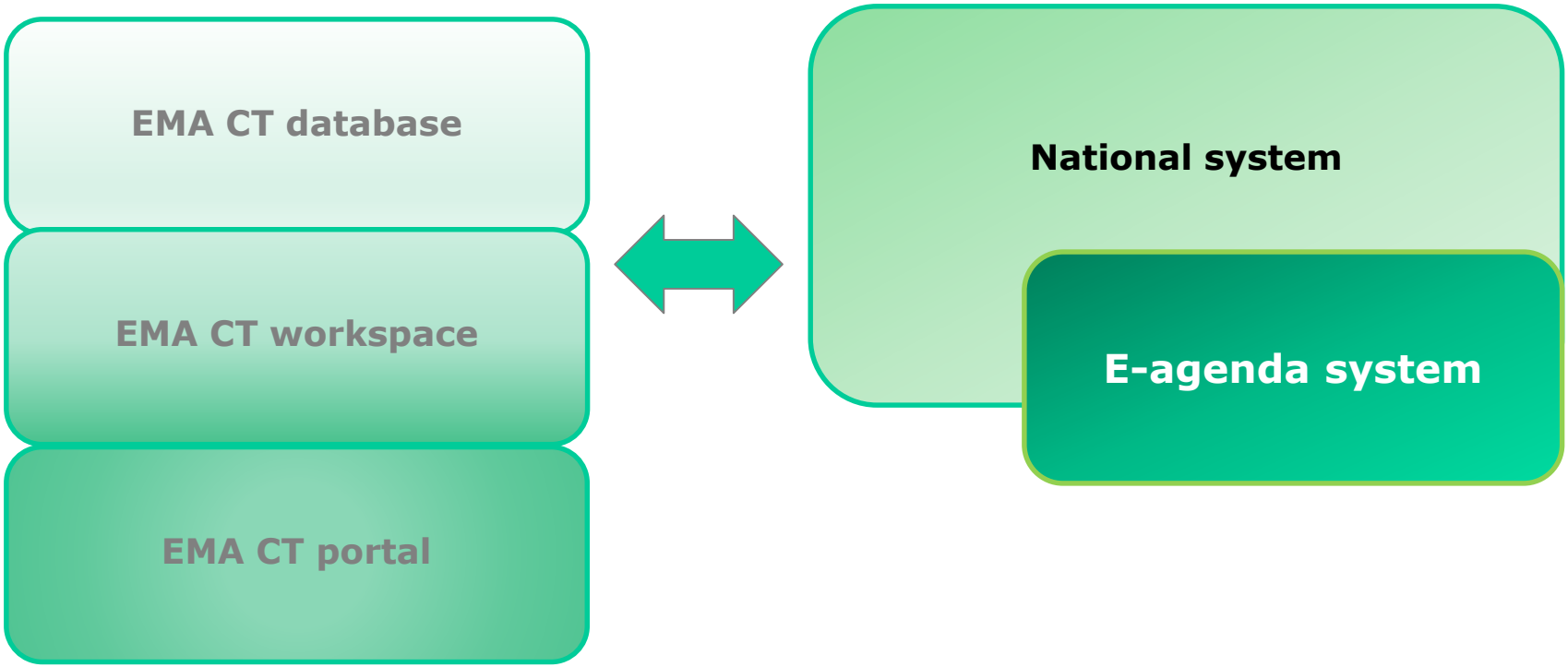
- Validation – 3 times within 10 days – response time down to 3 days
- Part I assessment – 3 times within 45 days, 6 times within 76 days – response time down to 5 days
- Single opinion – 1 time within 5 days

- *Ethics committee meetings every 12 days*
- *Dedicated and trained resources for coordination at DHMA and Ethics*
- *Ability to communicate in English*
- *National IT support is crucial and not supported by the EU portal and database unclear how much functionality the EU workspace will bring.*

Main challenges identified from the procedure

- Considerations at national level
  - Reorganisation of the ethics committees
  - Procedures to facilitate the work between the scientific authority (DHMA) and the ethics committee (short time-lines, competitive aspects – EU-level and global level)
  - Disclosure of information
    - Ensure the legal framework for exchange of information between EC and DHMA.
  - Financing – new fee structure? Level of the fees?

First shot on expected IT support



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Expected use of CT portal, database and workspace

EMA CT portal, database and workspace

Archive for data and documents and European assessments

Communication with MSCs, RMS and sponsor

Facilitate the generation of draft assessment reports and consolidating considerations into final assessment reports

Case management and workflow for multinational trials

Disclosure of information according to transparency rules

Reports and statistics on trials and cases

Needed functions of national IT system

National system

- Mirror EU workspace dashboard for national case management.
- Case creation integrated to the EU database, and creation of national workflow
- Common case handling system for DHMA and EC with separate domains
- Archive for national assessment of submissions
- Download of documents in the EU database (ad hoc and pre-defined packages).
- Upload of documents to EU database.
- Possible to make common documents.
- Interface of invoice and fee system.
- Direct access to EU database/portal/workspace.
- Integration to local MP and IMP database - Integrated to EP number.
- Generating Ad Hoc cases
- Report to case management system

E-agenda system

Facilitate involvement of EC and external assessors and EC planning of meetings

Needs for IT support – Control tower

Predicable planning of:

- Feed in to the part I assessment procedure as required for multinational trials for new trials and modifications
- Coordination with EC on all new trials and part I modifications
- Handle notifications and survail ongoing trials
- EC meetings
- Coordination of decisions with EC

Needs for IT support – Intelligence

- For planning of tasks
- For reporting of activities
- For statistics
- For surveillance of IMPs or trials

- Data quality and a good stable reporting tools is key success factors

Needs for IT support – Communication

- Communicate with sponsor and member states concerned in the EU portal
- Communicate and coordinate with EC in a national system
- Easy access to the overview and archiving
- Minimize communication outside of the system
- Avoid double work and registrations

Thank you

Questions