Promemoria Ds2016:12 on how to adjust evaluation of clinical drug trials in Sweden according to EU 536/2014

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The Case

Applications shall be submitted via an EU-portal at EMA

Member States must coordinate their evaluation

In Sweden MPA, the Medicinal Product Agency will provide the single opinion

The Ethical Review Boards will provide their assessment to MPA

Starting points

- The ethical evaluation will be done by a regional ethical review board according to the same principles as today

- Outcomes
  - →Approved
  - →Approved with conditions
  - →Not approved

Part I

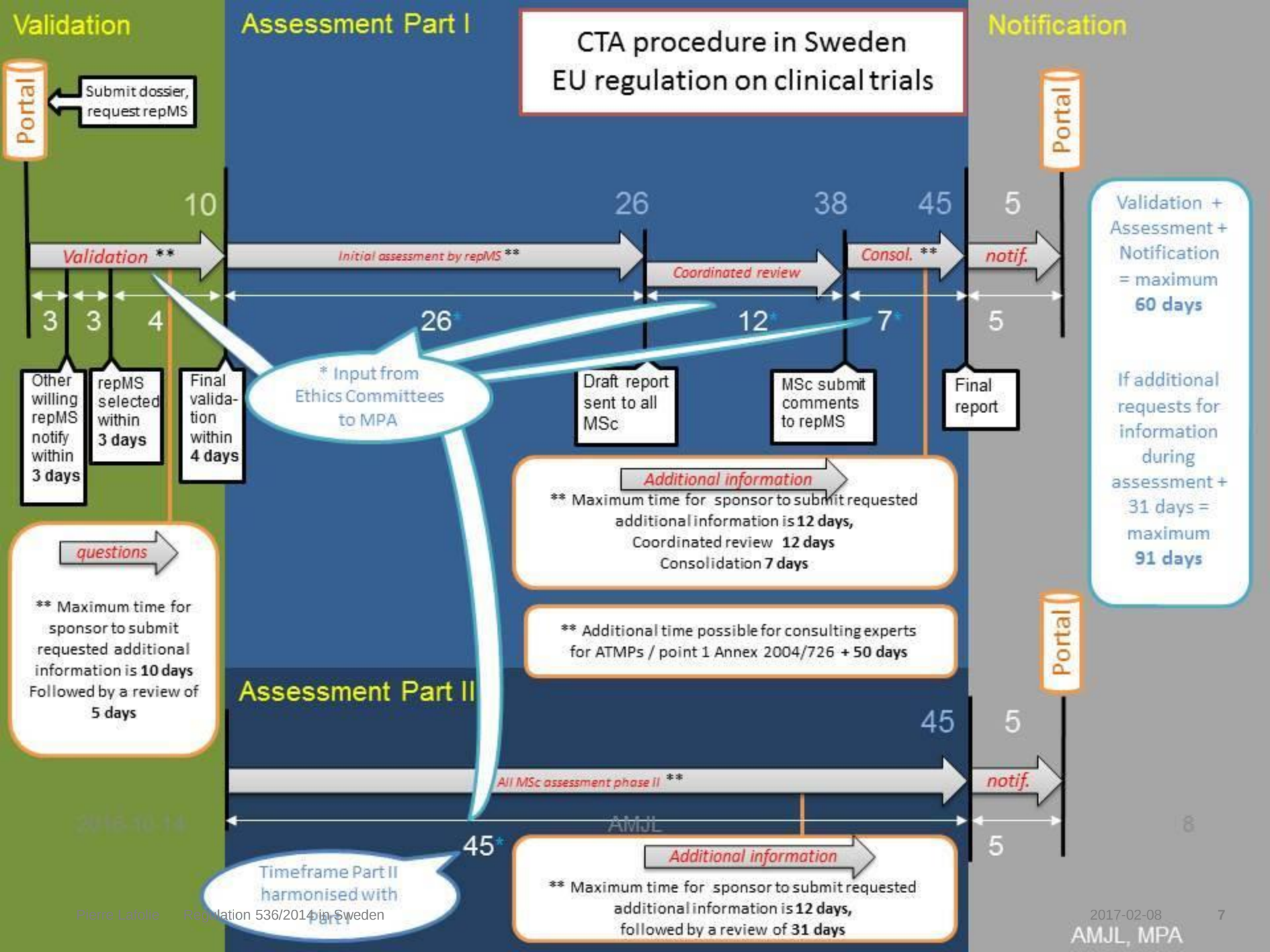
- Riskevaluation (low, median, high)
- Benefit vs. risk for participants
- Adherence to GMP
- Labelling
- Quality of Investigators Brochure

Part II

- Informed consent
- Remuneration to participants and researchers
- Recruitment of participants
- Ability of study team
- Conditions of premises
- Insurance
- Evaluation of handling sensitive personal data
- Evaluation of access, storage and future use of biological samples

Time-limits

- **Part I**
  - → **Stages**
    - 1 Validation < 10 days
    - 2 Preliminary evaluation < 26 days
    - 3 Consorted MS evaluation < 12 days
    - 4 Consolidation by reporting MS < 7 days
- **Part II**
    - Each MS deliver their opinion < 45 days
    - No opinion = approval


Validation
Assessment Part I
Notification
CTA procedure in Sweden
EU regulation on clinical trials
Portal
Submit dossier, request repMS
10
26
38
45
5
Validation **
Initial assessment by repMS **
Coordinated review
Consol. **
notif.
3
3
4
26*
12*
7*
5
Other willing repMS notify within 3 days
repMS selected within 3 days
Final validation within 4 days
* Input from Ethics Committees to MPA
Draft report sent to all MSc
MSc submit comments to repMS
Final report
Validation + Assessment + Notification = maximum 60 days
If additional requests for information during assessment + 31 days = maximum 91 days
Additional information
** Maximum time for sponsor to submit requested additional information is 12 days,
Coordinated review 12 days
Consolidation 7 days
questions
** Maximum time for sponsor to submit requested additional information is 10 days
Followed by a review of 5 days
** Additional time possible for consulting experts for ATMPs / point 1 Annex 2004/726 + 50 days
Assessment Part II
45
5
All MSc assessment phase II **
notif.
AMJL
45*
5
Additional information
** Maximum time for sponsor to submit requested additional information is 12 days,
followed by a review of 31 days
Timeframe Part II harmonised with Part I

Appeal

- Can be done to civil court

  →However…

  - Handling time might be much longer than 45 days, and no MS opinion = approval!

Some adminstrative routines

- Amendments - To the original ethical review board
- Referral to the national central ethical board will not be possible
- Patient organisations must participate in the decision
  →(today only laymen from political parties needed)
- Financial disclosure must be presented for all members and chairman

Inspection rights and fees

- With MPA
  - → Judging sponsor reports, tracking safety and evaluates risk / benefit ratio
  - → Deals with protocol violation
  - → May undertake inspections

- Only one fee, to MPA
  - → Ethical review board will have a share distributed from MPA

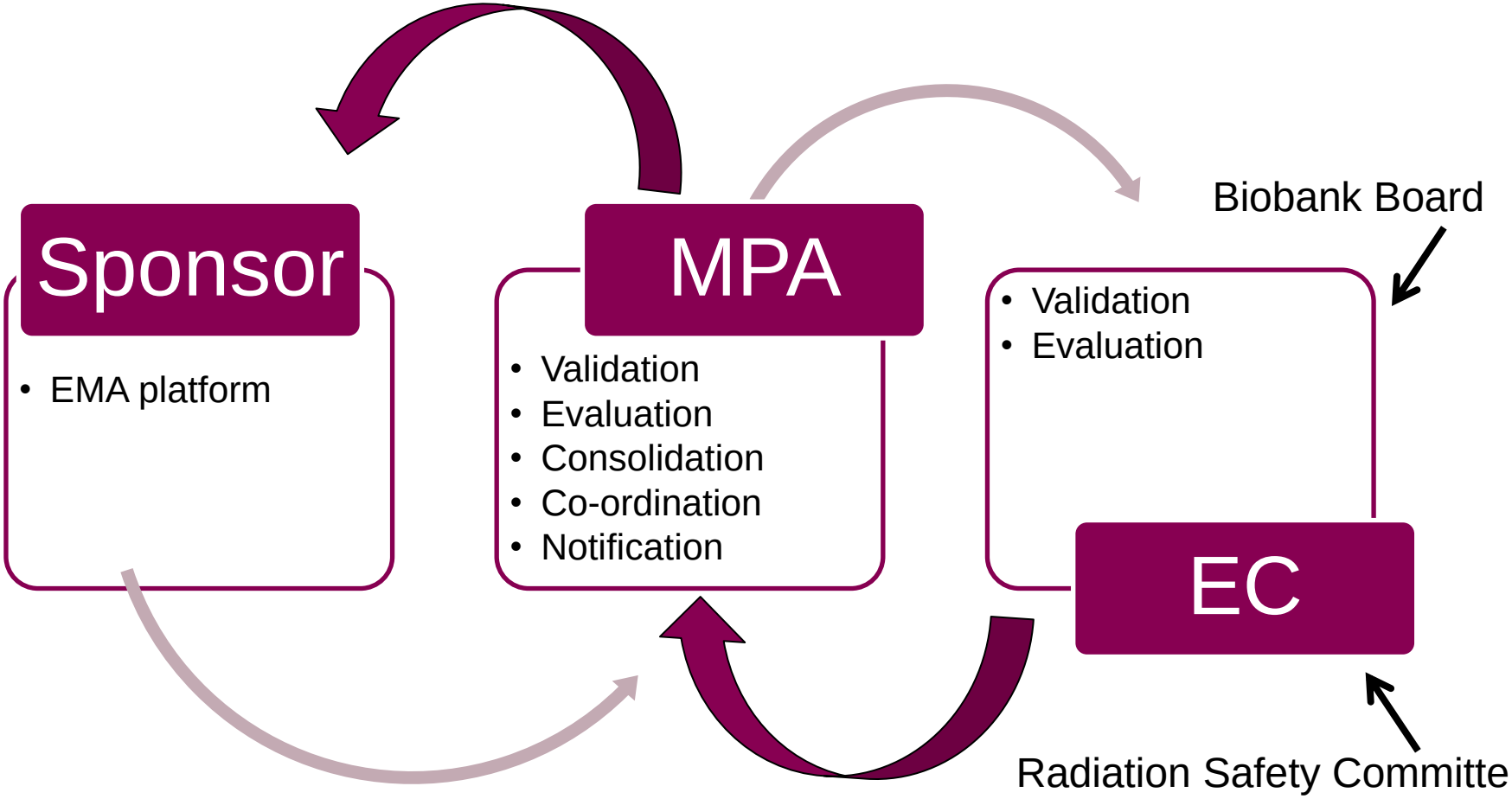
Information and communication

- Not yet decided by EMA, either
  - MPA have the only rights and distribute downstream
  - Ethical review boards have their own access
- Eudra link will be used for communication
  - EMA server
- The ethical review boards are presently creating an internal electronic document handling system (PRISMA)

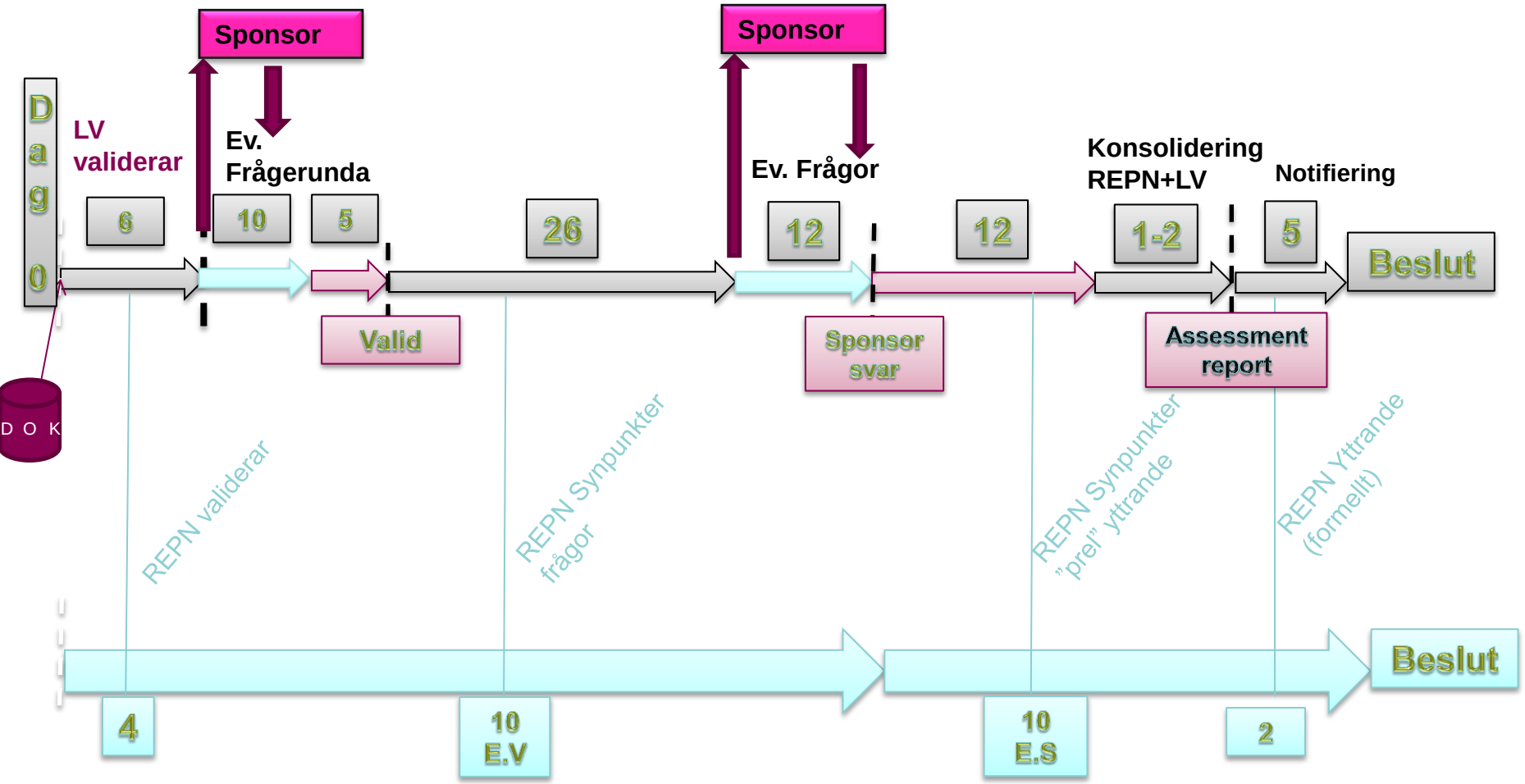
What is happening now in Sweden?

- A proposal for a new ethical review organisation is presented
  - → One department with local branches over the country
  - → To start 2018
- A new governmental investigation started Q4-16 on changes in the ethical review act, to be presented August 2017
- MPA is conducting a pilot study with the ethical review boards, starting Q1-17, tbc
- Unclear how interaction with Radiation Safety Committe and Biobank Boards shall be done

Swedish stakeholders evaluating applications for clinical studies



Time lines for Pilot to start Q1 2017



Thank you for your attention!

KI Aula Medica