Swedish Regulatory Authority Update on the National Activities Related to the EU Regulation

6th Conference on Clinical Trial in the Nordic Countries

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Revision of National Laws and Ordinances

- **Ongoing**
  - Ministry of Health and Social Affairs
    - Amendments to the Pharmaceutical Act
    - Amendments to the Public and Privacy Act
    - Amendments to the Trade in Pharmaceuticals Act
    - Amendments to the Biobanks in Health Care Act
  - Ministry of Education and Research
    - Adaptations in law regarding the ethics review of applications for clinical trials

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Revision of National Provisions (MPA)

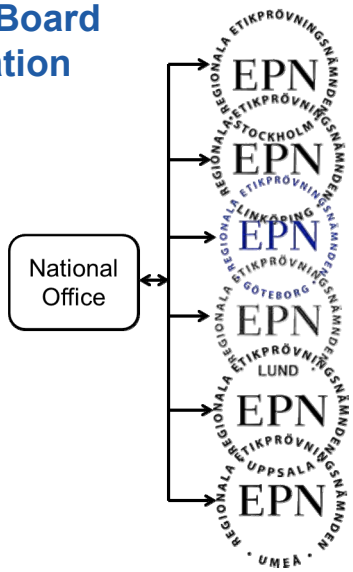
- **Not yet started**
  - Läkemedelsverkets föreskrifter om kliniska läkemedelsprövningar på människor (LVFS 2011:19) *(CTA)*
  - Läkemedelsverkets föreskrifter om partihandel med läkemedel (LVFS 2014:8) *(Trade)*
  - Läkemedelsverkets föreskrifter och allmänna råd om tillstånd för tillverkning och import av läkemedel (LVFS 2004:7) *(GDP)*
  - Läkemedelsverkets föreskrifter om god tillverkningssed för läkemedel (LVFS 2004:6) *(GMP)*
  - Läkemedelsverkets föreskrifter och allmänna råd om avsiktlig utsättning vid klinisk prövning av läkemedel som innehåller eller består av genetiskt modifierade organismer (LVFS 2004:10) *(GMO)*

Regional Ethics Review Board organisation

- **There are six regional ethics review boards**
- **Independent authorities, divided into two or more sections**
  - Make independent decisions on behalf of the regional board
  - Headed by a chairman who is a judge or has been one
  - Ten members with scientific qualifications and five to represent the general public, appointed by the government
  - In each section a scientific secretary is to be appointed from among the scientific members
  - Each of the sections is expected to have 10-12 meetings annually (every 4-6 weeks)

Regional Ethics Review Board Suggested new organisation

- The independent authorities merge into one national Ethics Review Board authority with one point of contact and six regional departments
- When.. 2018?



Government assignment for a new authorisation procedure for clinical trials (S2016/03981/FS) delivered 28th of April, 2017 1(3)

- **Collaboration and structure**
  - presenting possible forms of collaboration and structures for obtaining opinions from the Medical Product Agency, Regional Ethics Review Board, relevant biobanks and radiation protection committees regarding a CTA

Government assignment for a new authorisation procedure for clinical trials (S2016/03981/FS) delivered 28th of April, 2017 2(3)

- **Test in a pilot project**
  - The Medical Products Agency is instructed that, together with the six regional ethics review boards, also test the forms of collaboration in a pilot project. This is to ensure that the handling of the authorities effectively meets the requirements set out in the above mentioned EU regulation
  - In these pilot procedures, collaborative forms will also be tested to obtain opinions from biobanks and radiation protection committees to the relevant ethics review board

Government assignment for a new authorisation procedure for clinical trials (S2016/03981/FS) delivered 28th of April, 2017 3(3)

- **The Medical Products Agency makes final decisions**
  - The assignment includes that the Swedish Medical Product Agency is the authority which, on behalf of Sweden, takes the final decision on the authorisation of clinical trials
  - In each individual case, a regional ethics review board shall submit an opinion to the Medical Products Agency where the results of the ethical review of the application are stated

Resulted in a National CTA Pilot - conditions

- **Medical Product Agency (MPA)**
  - National point of contact for CTA
  - Validates the applications
  - Coordinates the assessments
  - Project leader of the pilot

- **Ethics Review Boards**
  - All six regional ethics review boards are participating
  - One single point of contact for the pilot at each board

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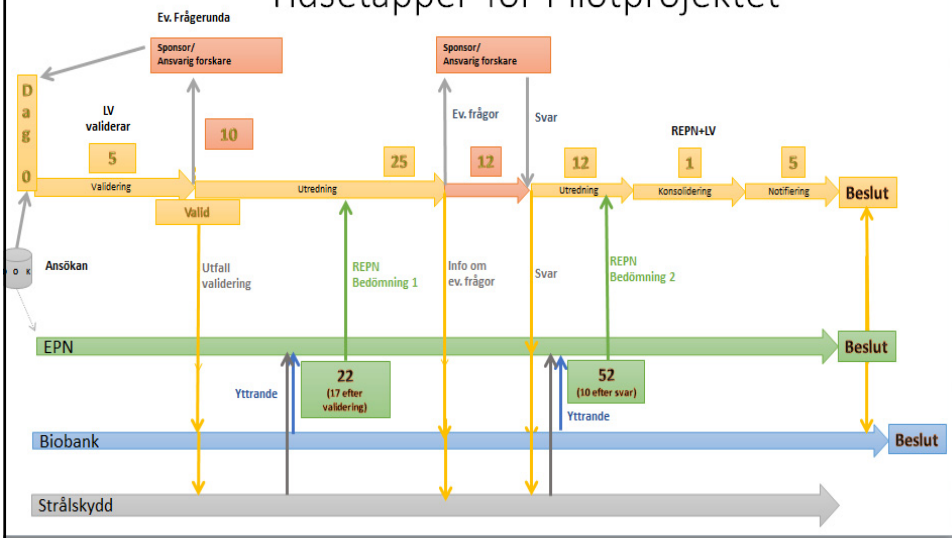
Tidsetapper för Pilotprojektet



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Government assignment for a new authorisation procedure for clinical trials in 2016

- **The Medical Products Agency makes final decisions**
  - The assignment includes that the Swedish Medical Product Agency is the authority which, on behalf of Sweden, takes the final decision on the authorisation of clinical trials
  - In each individual case, a regional ethics review board shall submit an opinion to the Medical Products Agency where the results of the ethical review of the application are stated

The Pilot Project

- **The pilot project is carried out and developed step by step**
- **Start, Q1 2017**
  - Working in segments with evaluation before stop/go decision
    - Q2 2017 - 2 CTA
    - Q3 2017 - 4 CTA , to be evaluated Q1 2018
    - Q1-2 2018 - ?

Continued Government assignment in June 2017..

Collaboration and structure

- **Continue to develop forms of collaboration and structures for obtaining opinions from the Medical Product Agency, Regional Ethics Review Board, relevant biobanks and radiation protection committees regarding a CTA**

Ends when the Regulation is in place

National Implementation Status

National Implementation Status - CTFG October 2017

	NCA - EC organisation	Ethics committees restructure	National law	National IT system	Fees	Communication and training	Pilot projects	Safety	Resources
AT									
BE									
BG							N/A		
CY									
CZ									
DE (BfArM, PEI)									
DK									
EE				N/A			N/A		
EL									
ES									
FI									
FR		N/A	N/A		N/A				
HR									
HU							N/A		
IE									
IS		N.A.					N.A.		
IT									
LI									
LT				N/A			N/A		
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LV				N/A					
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NO							N/A		
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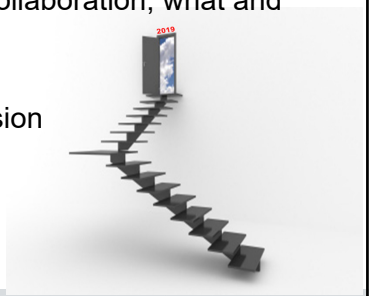
PT									
RO		N/A		N/A			N/A		
SE									
SI									
SK							N/A		
UK									

National challenges in summary..

- **Future organisation of Ethics Review Boards**
  - Number of ethic review boards and volumes of CTA/board
  - Meeting frequency (regularly, once monthly, non-physical)
- **The EU-portal..**
  - Will there be a space for national collaboration, what and when?
- **Fees**
  - Under discussion but no final decision
- **”Spreading the word..”**
  - Information and training



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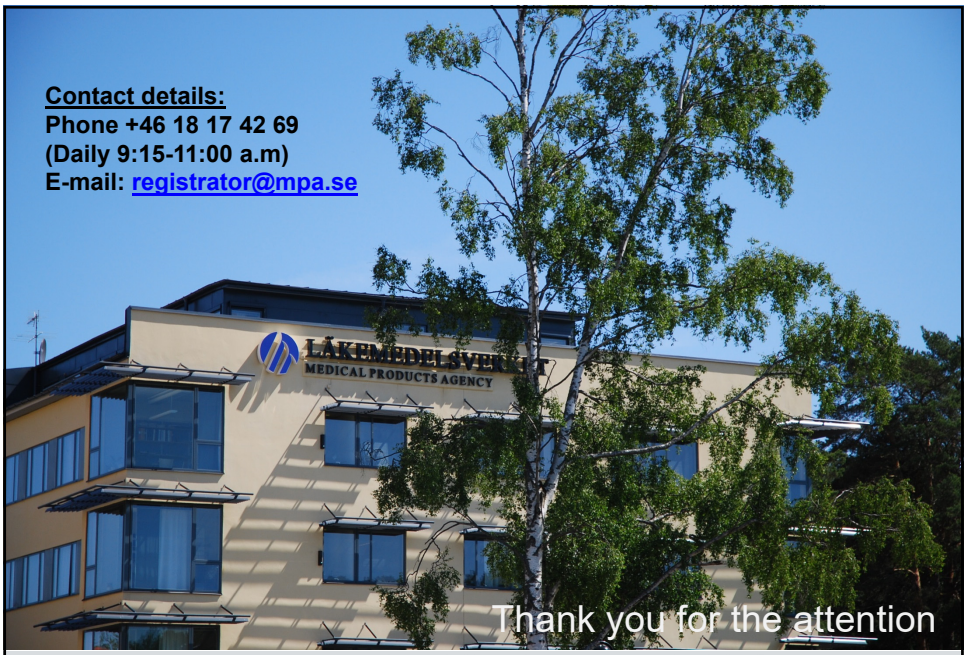

Thank you for the attention

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