Latest update and status from the National Medicines Agencies

- Gunilla Andrew-Nielsen

- Ingvild Aaløkken

- Lene Grejs Petersen

- 7 th Conference on Clinical Trials in the Nordic Countries 2019

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

1

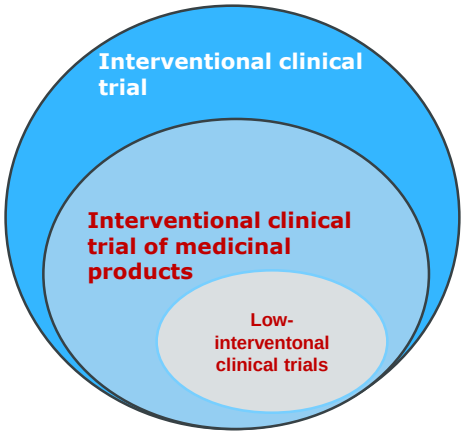
Latest update and status from the National Medicines Agencies

- Introduction to the Clinical Trials Regulation
- How far are we in Norway, Sweden and Denmark
- Pilots for the Clinical Trials Regulation

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

2

Scope of the Clinical Trial Regulation (CTR)

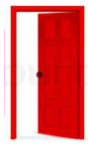


- Harmonised dossier, single submission, coordinated assessment, reporting
- Submission and Workflow through EU Portal/Database
- Risk-based approach
- To attract clinical trials to EU

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

3

Key changes from the CT Regulation



- **Single e-submission to all Member States (MS)** via an EU portal (accessible to MS NCAs and ethics committees). To be developed and managed by EMA.
- **Harmonised dossier** (Annex I to the Regulation / language of the documents decided by each MS).
- **Coordinated assessment** between reporting MS and concerned MSs.
  - MS Coordinated assessment between NCA and ethics.
- One **single** Member State **decision**
- **Tacit decision** for the single decision

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

4

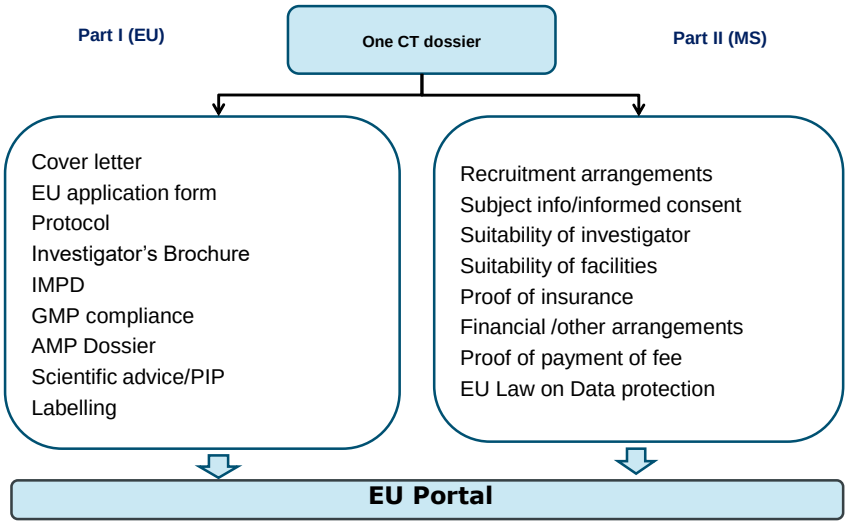
Key changes from the CT Regulation

- Introducing a **risk adapted approach** by applying less stringent rules to those trials conducted with medicines which are already authorised and which pose only minimal risk compared to normal clinical practice.
- **Increasing transparency** as regards clinical trials and their outcomes.
- **Simplifying safety reporting requirements.**
  - Reporting to Eudravigilance

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

5

Application dossier

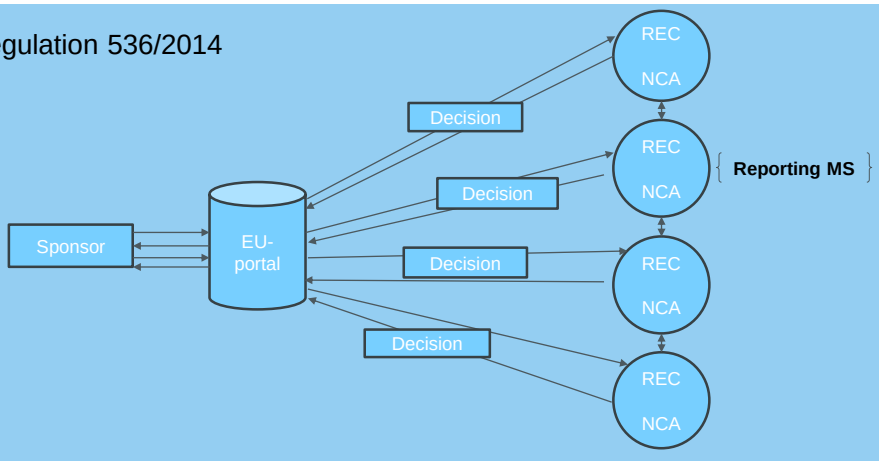


LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

6

Application procedure for CTR

– Regulation 536/2014



7 14. NOVEMBER 2019

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

7

National Implementation Status - CTFG October 2019

NCA - EC organisation	Ethics committees restructure	National law	National IT system	Fees	Communication and training	Pilot projects	Safety	Resources
			N/A	N/A		N/A		
			NA			NA		
			N/A					
	N/A	N/A		N/A				
?			?	?	?	?		?
			?					
	N.A.					N.A.		
			N/A			N/A		
			N/A					
			N/A					
						N/A		
	N/A		N/A			N/A		
			N/A					

The color used should reflect the *current status of progress* ***against*** *the member state implementation plan:*

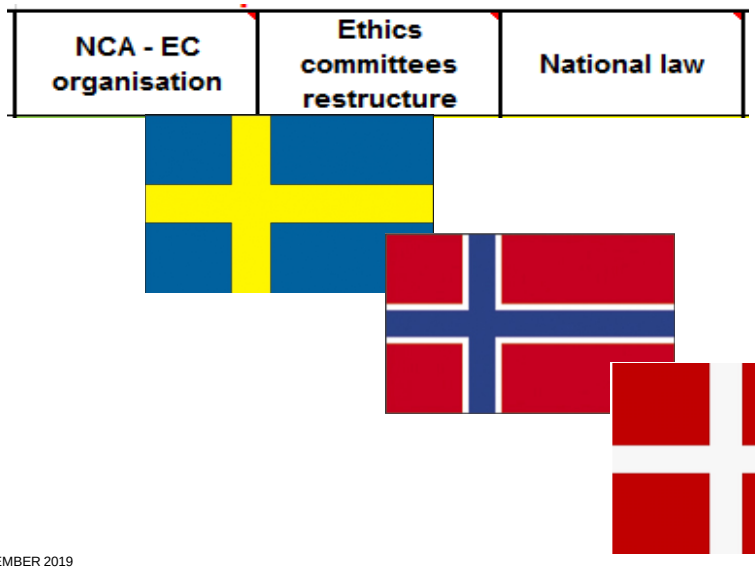
Little progress, major hurdles remain, Some progress, more activity needed, Progressing well, on target

8 14. NOVEMBER 2019

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

8

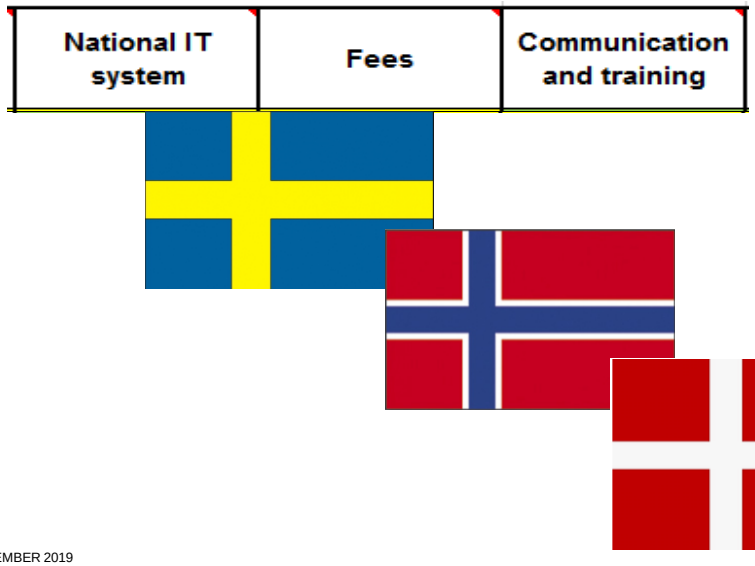
National Implementation Status - CTFG October 2019



LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

9

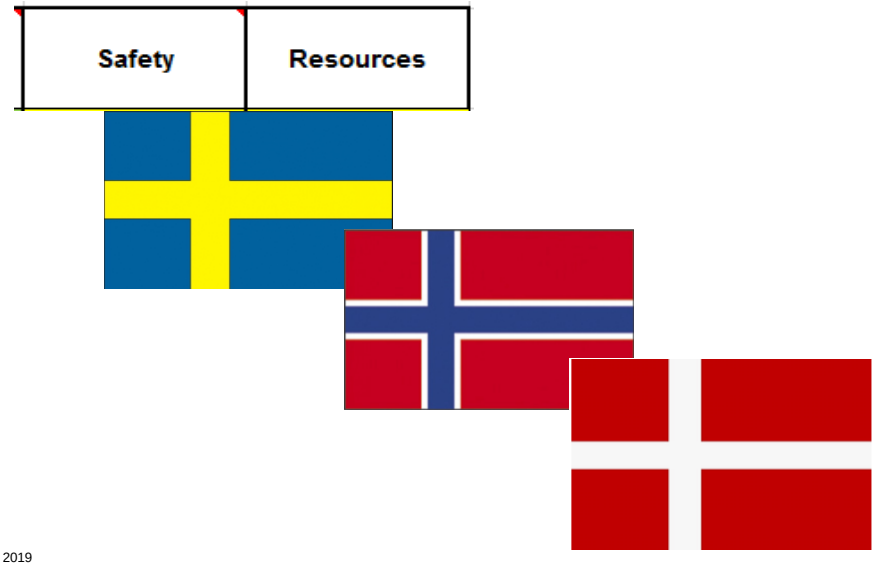
National Implementation Status - CTFG October 2019



LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

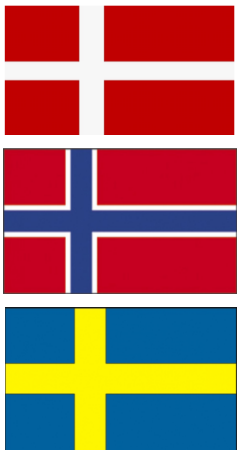
10

National Implementation Status - CTFG October 2019



LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Pilots for the Clinical Trial Regulation



- DK: VHP-plus for trials with children, ATMP and phase I-II oncology trial
- NO: VHP-plus
- SE: National pilot

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Transitional periods

Following the application of the Regulation:

- For 1 year it will be possible to file an application under the current rules or the new rules (e.g. ultimo 2020-ultmo 2021);
- For 3 years CT authorised under 2001/20 will continue to be governed by the old rules (e.g. ultimo 2023).
- Guidance:
  - On document updates: CTFG website
  - On procedure: EU Commission Volume 10, Q&A, chapter 11.

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Thank you – Question?

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Statens legemiddelverk

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Følg os

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY