Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency

Status of CTR implementation preparation in Finland

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Safety

- Fimea has started Safety reporting MS-roles in 2019
- Fimea has started to use VHP DSUR AR:s in assessment of nationally submitted DSUR:s
- Sufficient competence expected to be gained trough VHP participation by time of CTR implementation

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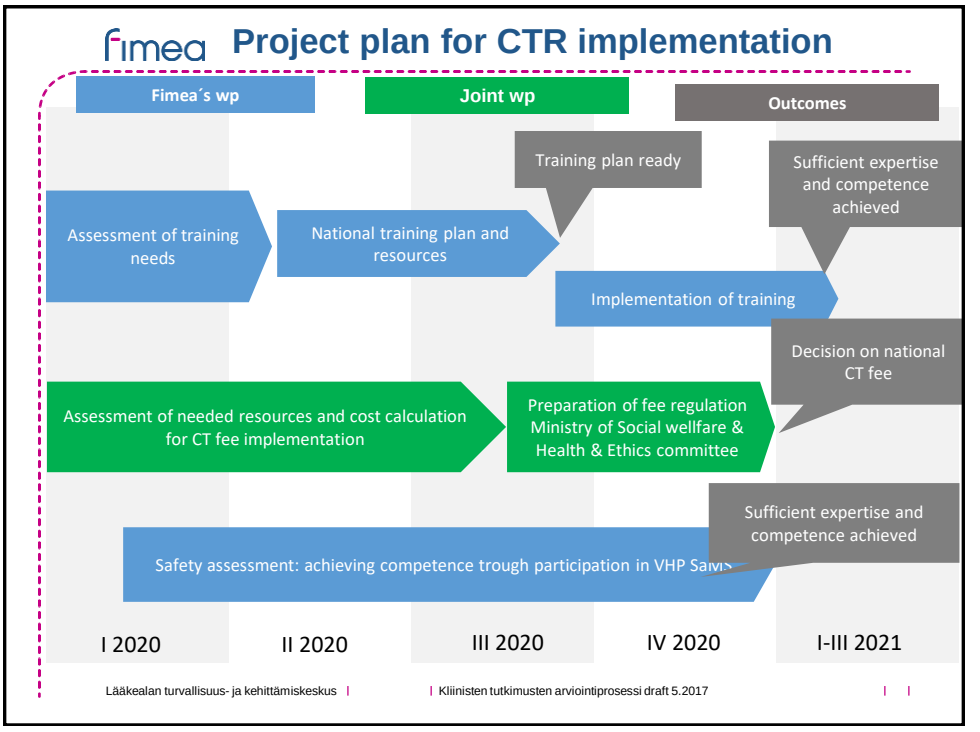
Project plan for CTR implementation
Fimea´s wp
Joint wp
Outcomes
Training plan ready
Sufficient expertise and competence achieved
Assessment of training needs
National training plan and resources
Implementation of training
Decision on national CT fee
Assessment of needed resources and cost calculation for CT fee implementation
Preparation of fee regulation Ministry of Social wellfare & Health & Ethics committee
Sufficient expertise and competence achieved
Safety assessment: achieving competence trough participation in VHP Saimi
I 2020
II 2020
III 2020
IV 2020
I-III 2021
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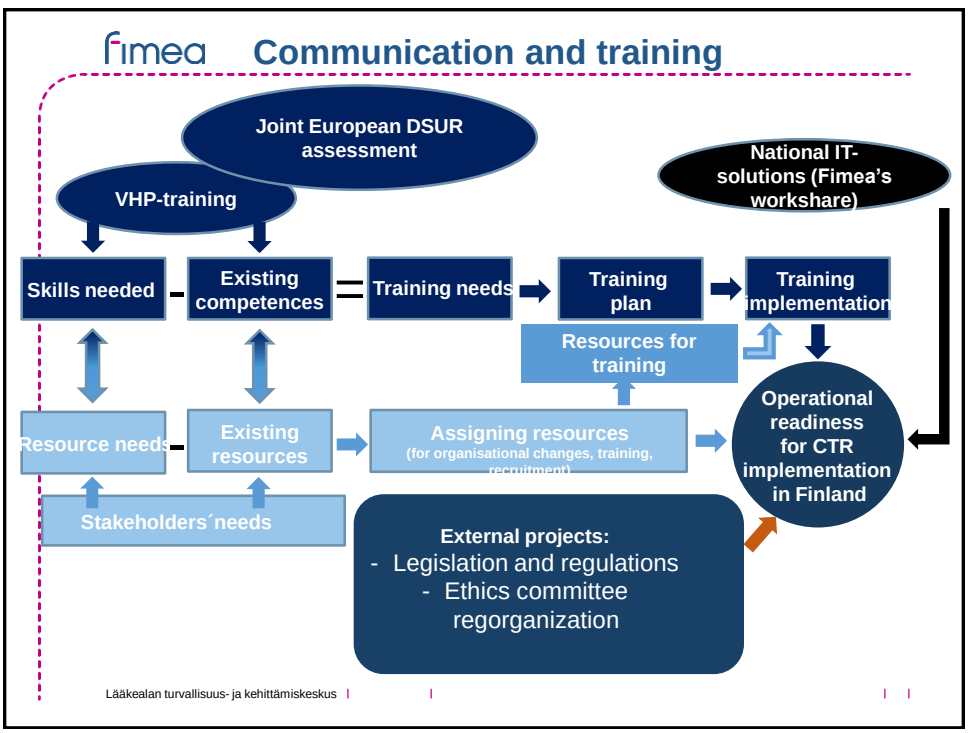
Kliinisten tutkimusten arviointiprosessi draft 5.2017

3


Communication and training
Joint European DSUR assessment
VHP-training
National IT-solutions (Fimea's workshare)
Skills needed
Existing competences
Training needs
Training plan
Training implementation
Resources for training
Resource needs
Existing resources
Assigning resources
(for organisational changes, training, recruitment)
Operational readiness for CTR implementation in Finland
Stakeholders´needs
External projects:
- Legislation and regulations
- Ethics committee regorganization
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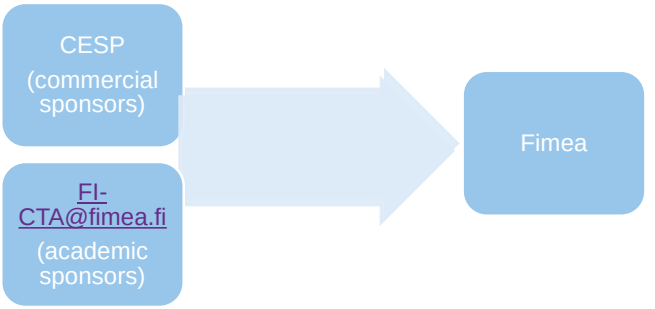
National IT system

- Work in progress: preparation for fully electronic submissions (estimated: Jan/2020) pre- CTR & transition period
- Electronic archiving
- IT Solutions for communication systems with Ethics committee not yet solved



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Fees

- Fees wíll be decided by Ministry of Social Affairs and Health, Ethics committee and Fimea
- Work-time calculations in place in Fimea for VHP processes (in different roles + amendments, safety assessments etc)

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Pilot projects

- SOP for National pilot (Fimea+ Tukija) was agreed ->joint assessment has not started due to Tukija´s resource issues
- Fimea started a pilot as own project Oct 2019 (implementation of CTR templates and timelines): voluntary for sponsors to participate; so far 2 applications have been piloted
- Fimea has participated in VHP:s since 2015
  - Q1-Q3/2019 New VHP applications: 4 Ref- NCA roles, 13 P-NCA roles = 17 new VHPs
  - Q1-Q3/2019 VHP Amendments: 9 Ref-NCA roles, 71 P-NCA roles = 80 VHP Am:s
- More experience needed

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National law

- National law expected to be submitted for approval by the parliament by end of 2019
- Some sections are intended to be applied already in 1/2020
  - These sections concern implementation of the GDPR in both clinical trials and other medical research
- Object of national legislation is to create flexible and research friendly environment
- Accepted languages for applications: Finnish, Swedish and English
  - Materials for the subject must be in Finnish/Swedish

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Ethics committee's structure

- Outlined in National Law
- Resources for implementation and practice in VHP+ pending
- There will be one national ethics committee to assess all clinical trials, operating by the National Supervisory Authority for Welfare and Health
- Committee will be appointed for 4 years at a time
- There must be experts in clinical trials, medicine, statistics, ethics and law (plus one layperson) in the Committee
- The Committee must include a chairman + at least 30 other members (pool of experts)
  - The Committee can also use permanent or temporary experts from outside the Committee
- In addition to assessing clinical trials applications, the Committee has other tasks defined in legislation, such as acting as an expert in ethical questions and taking part in international cooperation

NCA-EC organization

- Assessment of an application will be independent in NCA and EC but the two will collaborate in order to ensure high quality assessment and fluency of the process
  - The EC can express its' views for the NCA concerning validation of an application
  - The EC can take part in finalizing part I of the assessment report
  - The EC and NCA can advise each other in questions concerning an application or common scientific, ethical, legal or practical issues
  - Fimea can express views/comment to part II
- The NCA must take into account the views of the EC