CTR training
Member State preparedness and national aspects

Finland

Dr Pirjo Inki, MD, PhD

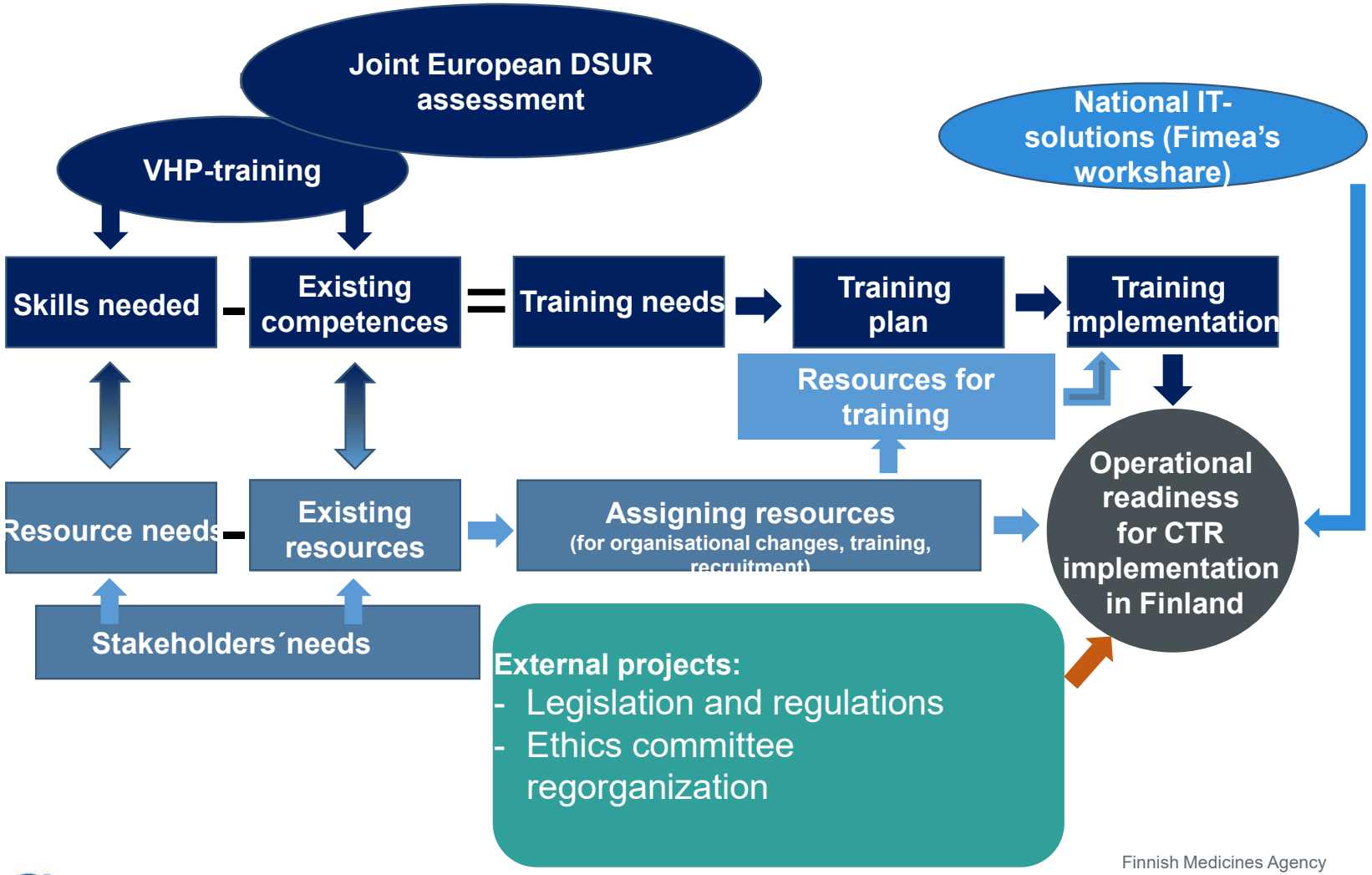
Head Clinical Trials

Finnish Medicines agency FIMEA

Contents

- Training plan; results of training survey and national training plans
- Ethics committee restructure
- IT solutions
- Legistlation & fees

Communication and training

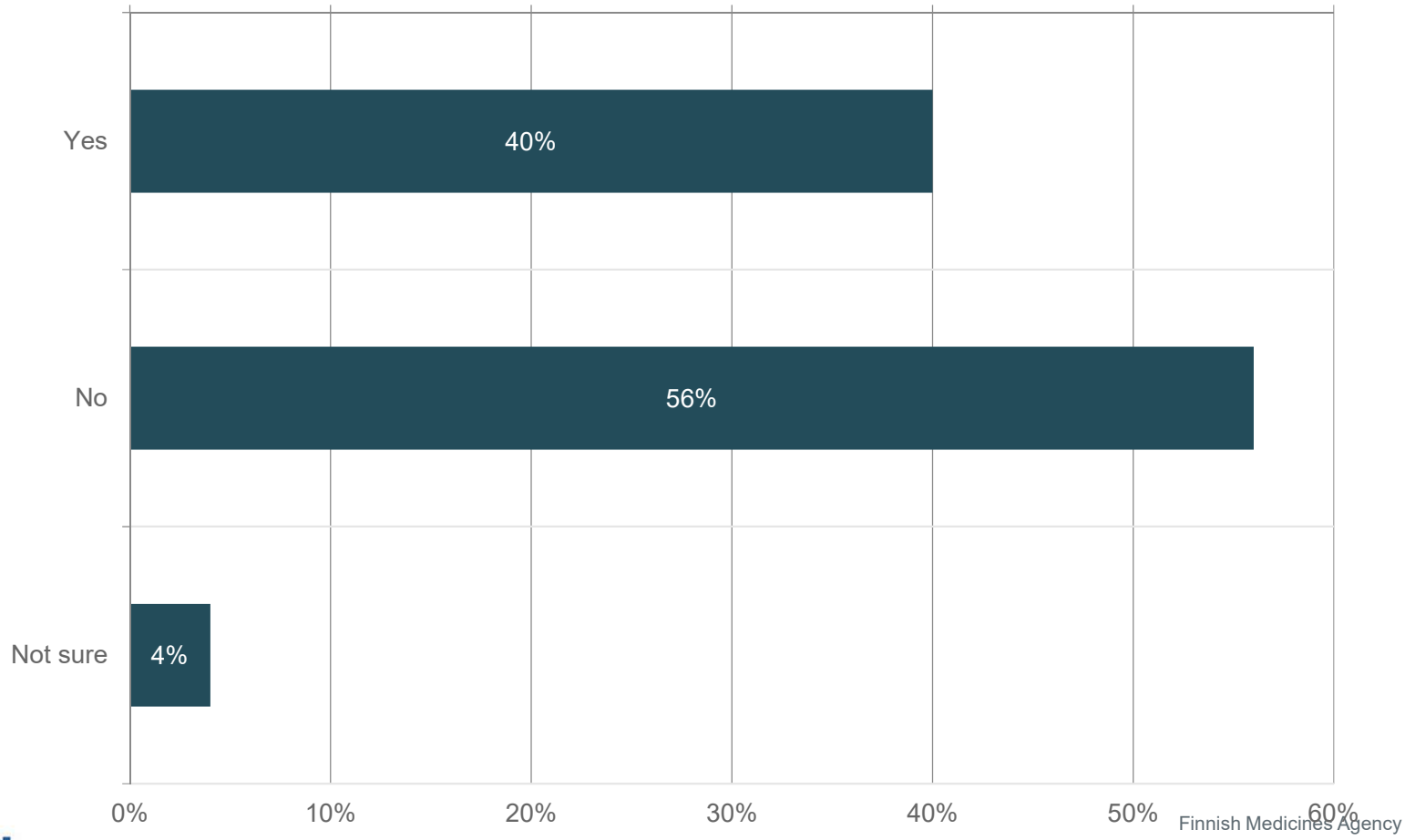


Training survey among employees at Fimea

- Conducted as a targeted online survey in Spring 2020 to Fimea´s employees
- Respondents n=56
- Intended to support national training plan
- Background of respondents: clin & quality assessors, gcp inspectors, legal officers, co-ordinators

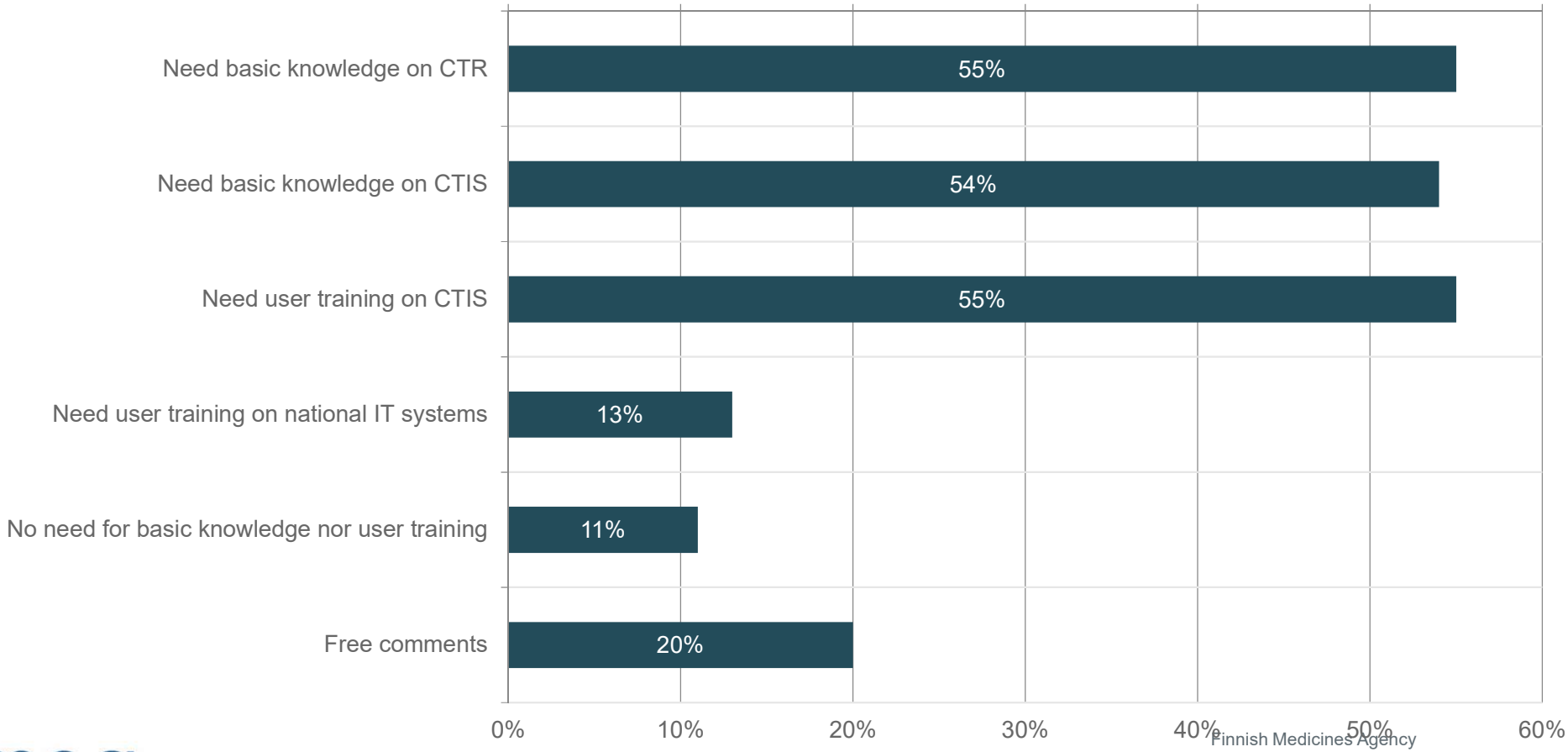
Have you participated in VHP?

N=55



Training needs (choose one or more options)

N=56, N of answers=116



Lessons learned

- VHP experience is crucial
- Most respondents need both training on CTR and CTIS
- Preferred learning method: self-guided modules or supervised online training. Some preferred F2F training
- Need for resources for ad-hoc support by admin/ co-ordinators
- Also personnel not directly involved in evaluating clinical trials would need basic training on CTR
- Special modules for GCP inspectors needed

National training plan

- Use of CTR training materials + CTIS modules. No national training materials developed
  - Exception: for occasional users, simple guides for critical steps planned
- Two categories of users: heavy and ”occasional”
- Identification of modules with most critical content per user groups
- Prepare for on-line support by admin/co-ordinator during critical steps

	Co-ordination	Clin/Stat assessors	Quality/Pre-clin assessors/Inspect
Module 1: Introduction to the Clinical Trials Regulation (EU) No 536/2014	+	+	+
Module 2: Overview of CTIS workspaces and common system functionalities	+	+	+
Module 3: User Access Management	+	+	
Module 4: Support with workload management by workspace	+	+	
Module 5: How to manage a Clinical Trial	+	+	
Module 6: How to evaluate a Clinical Trial application	+	+	
Module 7: Management of registered users and role matrix	+	+	
Module 8: Evaluate a CTA - Assessment and decision-making	+	+	+
Module 9: Sponsor search, view and download a Clinical Trial	+	+	
Module 10: Create, submit and withdraw a Clinical Trial and address responses to Requests For Information	+	+	

	Co-ordination	Clin/Stat assessors	Inspectors
Module 11: Clinical Study Reports submissions	+	+	
Module 12: Supervise a Clinical Trial - Corrective Measures	+	+	+
Module 13: Member State search, view & download a Clinical Trial	+	+	
Module 14: Ad hoc assessments	+	+	
Module 15: Create, submit and address responses to Requests for Information of Annual Safety	+	+	
Module 16: Assess an Annual Safety Report	+	+	
Module 17: Supervise a Clinical Trial – Additional information assessment (safety related)	+	+	
Module 18: Supervise a Clinical Trial – Inspection records			+
Module 19: Manage Union Controls			+
Module 20: Business Intelligence Reporting			
Module 21: Introduction to CTIS for Public Users			

Ethics committee re-structure

- Outlined in National Law
- There will be only 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
- Electronic applications started 2021, online meetings started in 2020

EC-NCA interaction

- Both EC and NCA participate in part I and II
- 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
- National pilot started Nov 2020

EC-NCA interaction

- Single decision (issued by Fimea)
- Fees split between EC and Fimea
- Experience from national pilot needed to gain experience on interaction

National IT system

- Shift to electronic submission started in 2019, since Jan 2020 all materials and correspondence with sponsors. Electronic signatures from sponsors accepted, Fimea´s decision forms electronically signed
- Academic sponsors use secure e-mail, commercial sponsors use CESP
- Plan to automised download of materials needing permanent archiving by national law from CTIS
- National pilot uses a sharepoint site for materials to be shared with EC, single submission of all materials by sponsor

National legislation

- Under parliamentary review
- Accepted languages for applications: Finnish, Swedish and English
  - Materials for the subject must be in Finnish/Swedish
- Fees: Only one common fee may be charged for the ethical and scientific evaluation of a clinical trial. The payment will be divided between the EC and Fimea.

National legislation aspects

- Implementation of the GDPR in both clinical trials and other medical research
- Vulnerable populations
  - **Defenition of an incapacitated subject**: A person who, owing to a disease, disability, or other similar reasons, is incapable to understand the information provided in accordance with Art 29 CTR, in such a way that he/she would be able to independently give informed consent to participate in the trial
  - **Minors**:
    - Informed consent requred from the minor's guardian or other legal representative; a parallel written consent from the minor's is also required if the minor is capable of forming an opinion and evaluate the trial-related information
    - A 15-year-old subject may give an independent informed consent to participate in a trial referred to in Art 32(1)(g)(i) CTR (=*participation in the clinical trial will produce a direct benefit for the minor concerned outweighing the risks and burdens involved*)
  - **Prisoners or forensic psychiatry patients** may be research subjects only where the research is likely to be of direct benefit to their own health or the health of people related to them or the health of other prisoners or forensic psychiatry patients