Virtual elements in clinical trials

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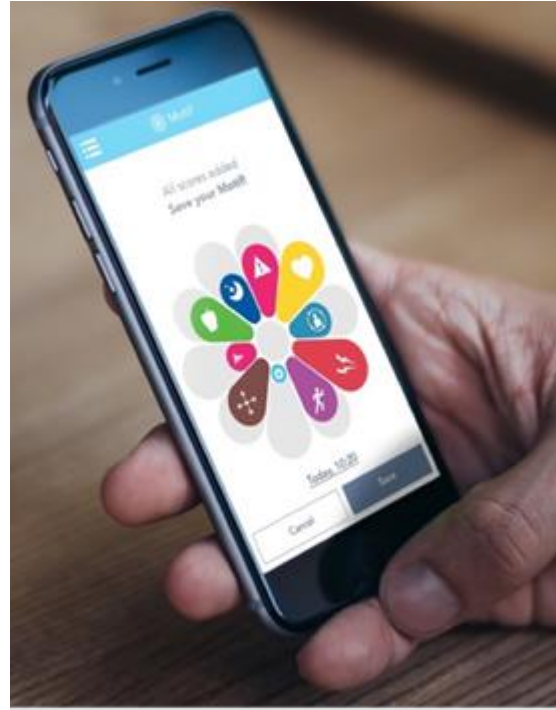
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- Henna Mäkelä Novartis

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Patient and Site Centricity

Pinching test   Draw Shape test   U -turn test   2 -minute walk test   Cognitive test

Please rate your pain during or after the passing of bowel movements, at its WORST, in the past 24 hours

NA – no bowel movement in the past 24 hours

0	1	2	3	4	5	6	7	8	9	10

No Pain

Pain as bad as you can imagine

Electronic patient reported outcome (ePRO)

Different devices, Apps & questionnaires

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Remote visits: via Phone, Video (Teams, Zoom etc.)

Home visits/other Health Care Unit visits; Laboratory samples & other Protocol related measurements

IMP home delivery

Remote Monitoring and Audits (eCRF, eISF)
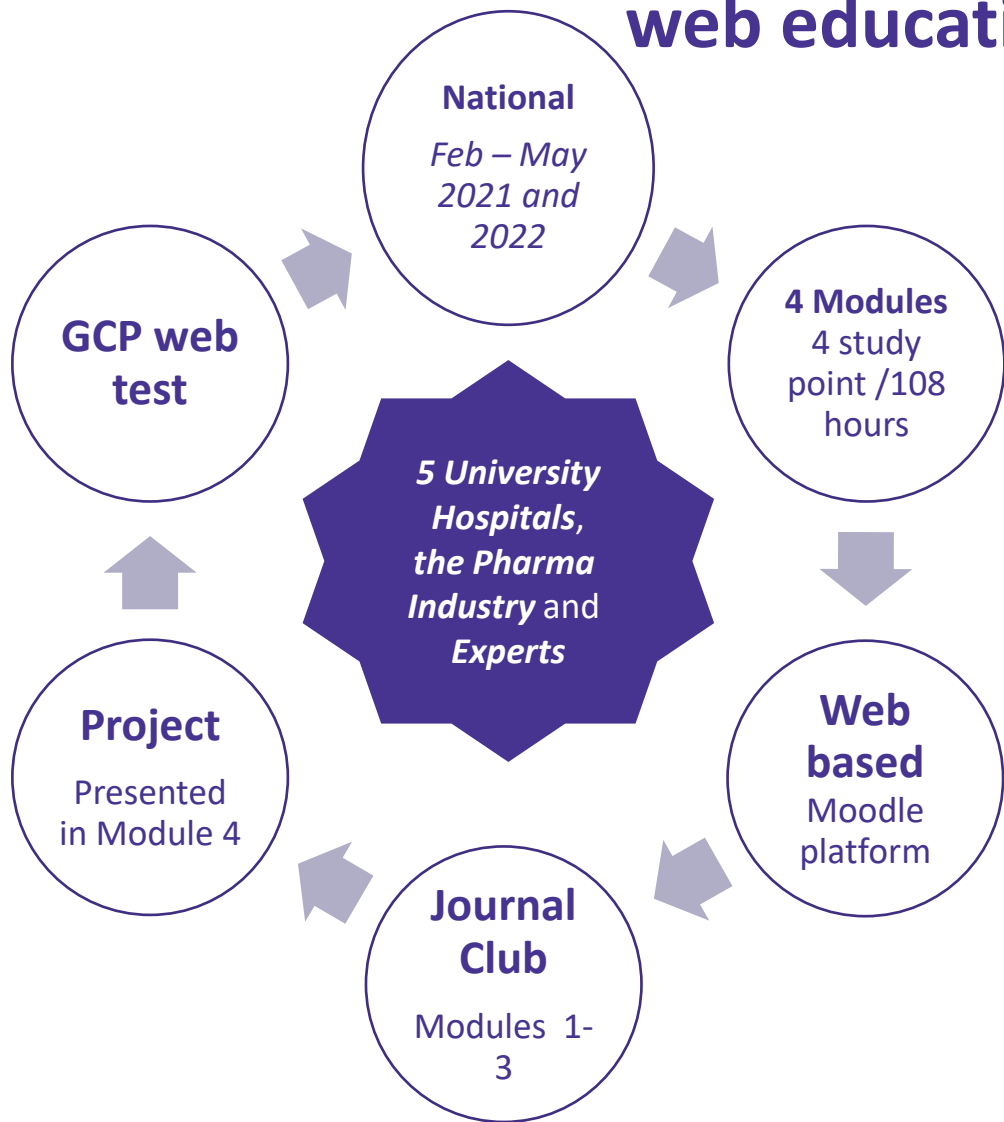
e-Informed Consent Form

Decentralized trial Elements

Why Nordics?

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Widespread use of smart devices and No excess logistics needed to deliver devices

High compliance and low drop our rate

High level of basic education

Willingness to participate in clinical trials is high

Well working collaboration with the local Authorities

Essential with Clinical Trial Regulation -CTR

22.6.2022

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National Study Coordinator
web education program in Finland

National
Feb – May 2021 and 2022

GCP web test

4 Modules
4 study point /108 hours

5 University Hospitals, the Pharma Industry and Experts

Project
Presented in Module 4

Web based
Moodle platform

Journal Club
Modules 1-3

Lisämateriaali

Yleinen Chat

Moduuli 1: Lääkekehityskaari

Moduuli 1: Tutkimusetiikka

Moduuli 1: Yhteistyö tutkija…

Moduuli 1: Tutkimushoitaja…

Moduuli 1: Digitaalisuus lää…

Moduuli 1: Journal club

Moduuli 1: Chat

Moduuli 1: Palaute

Moduuli 2: Hyvä kliininen tu…

Moduuli 2: Tutkimuksen osa…

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Kiitos/Thank you