

HEU-EFS - Harmonised approach to Early Feasibility Studies for Medical Devices in the European Union

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Rilevanza degli EFS

2013

- FDA pubblica guidance e istituisce programma EFS dopo fase pilota.

2020

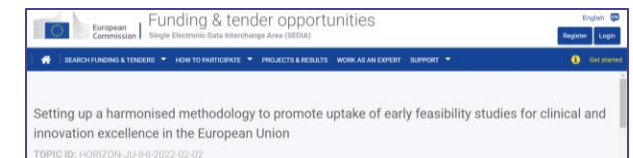
- EFS tra le indagini cliniche pre-market previste da ISO 14155 Clinical investigation of medical devices for human subjects – Good clinical practice.

2021

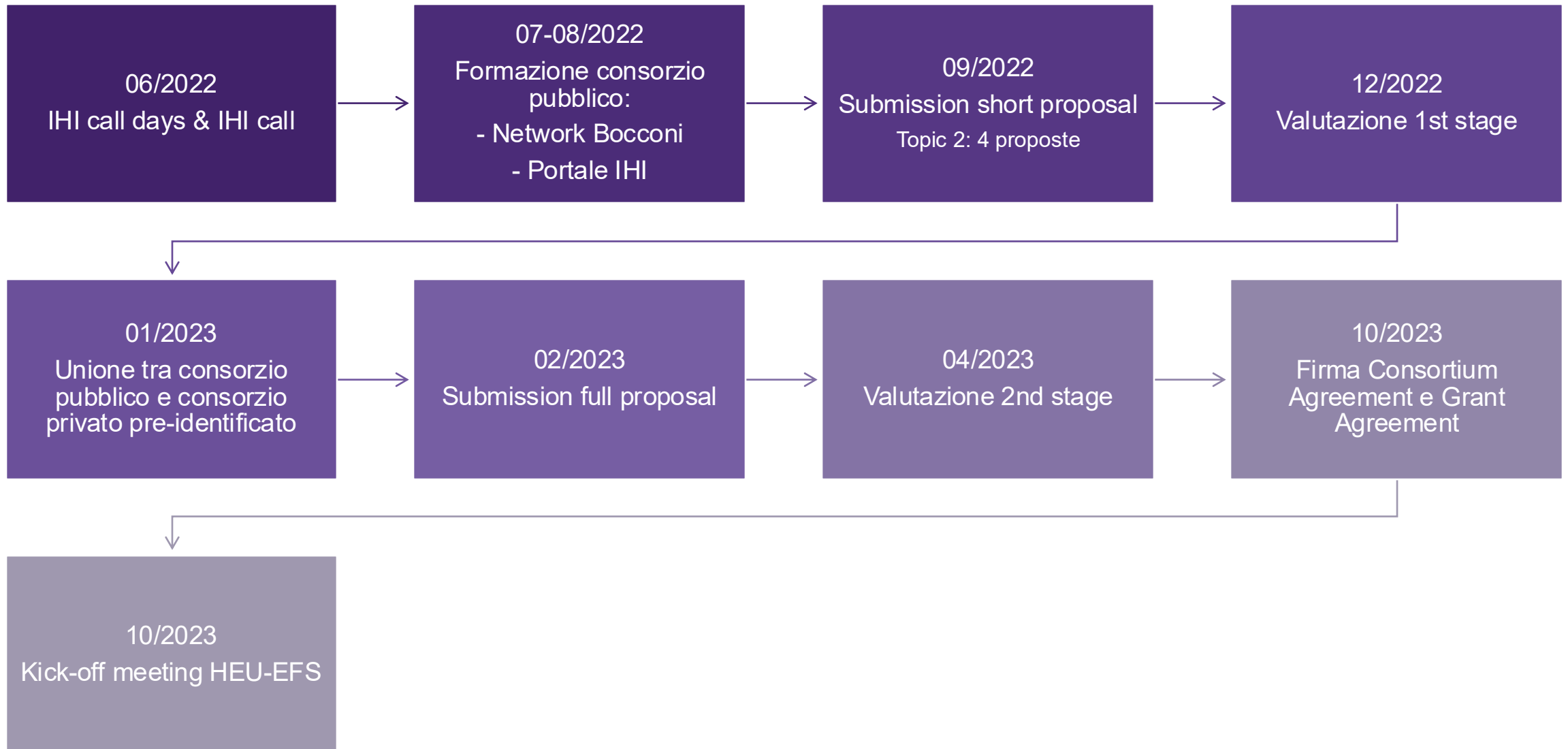
- EFS tra le pilot clinical investigation previste da MDCG 2021-6 Regulation (EU) 2017/745 – Q&A regarding clinical investigation.

2022

- Call Horizon - Innovative Health Initiative Joint Undertaking.



Storia del progetto



Consorzio

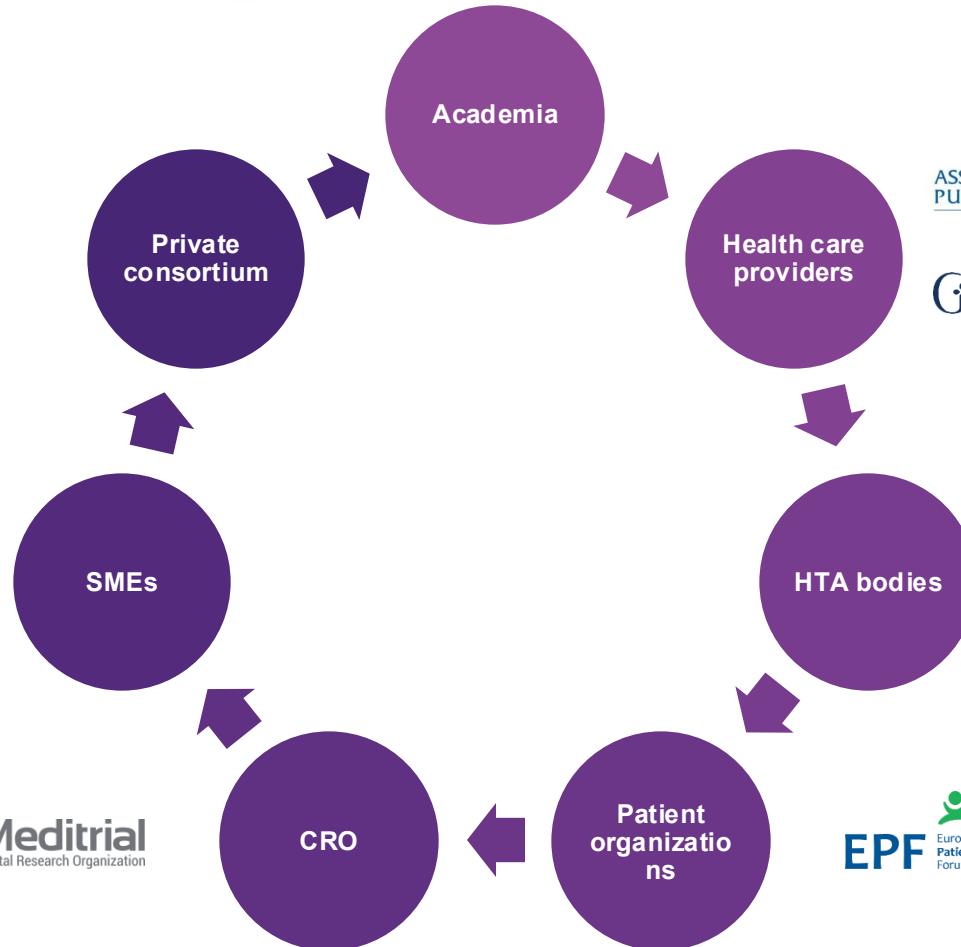


Consortio

12 Paesi: 9 EU (BE, DE, DK, ES, FR, IE, IT, NL), 1
EEA (NO), 3 non-EU (UK, CH, US).



Bocconi (leader of the Consortium)



Medtronic



Il progetto HEU-EFS si propone di sviluppare un approccio armonizzato per gli EFS per dispositivi medici nell'Unione Europea

- 1** Condurre ricerca e analisi sullo stato dell'arte del contest regolatorio e sulle caratteristiche dei programme pre-market.
- 2** Costruire un network sostenibile di stakeholders che promuova l'implementazione degli EFS nell'UE.
- 3** Sviluppare una metodologia europea solida e armonizzata e formulare raccomandazioni per l'adozione degli EFS.
- 4** Condurre progetti pilota finalizzati a testare e migliorare il framework metodologico proposto.
- 5** Sviluppare strumenti per il monitoraggio della performance del programma europeo di EFS.
- 6** Implementare un portale sostenibile e open access dedicato agli EFS e disseminare risultati e raccomandazioni del progetto.

Struttura del progetto

WP 9
Scientific supervision and project management

WP 1
Research and analysis on state of play of pre-market programs and implementation barriers to EFS

WP 2
Research and analysis on regulatory framework and organization of clinical evidence generation programs in the EU

WP 3
Methodology development: rationale, processes, and procedure

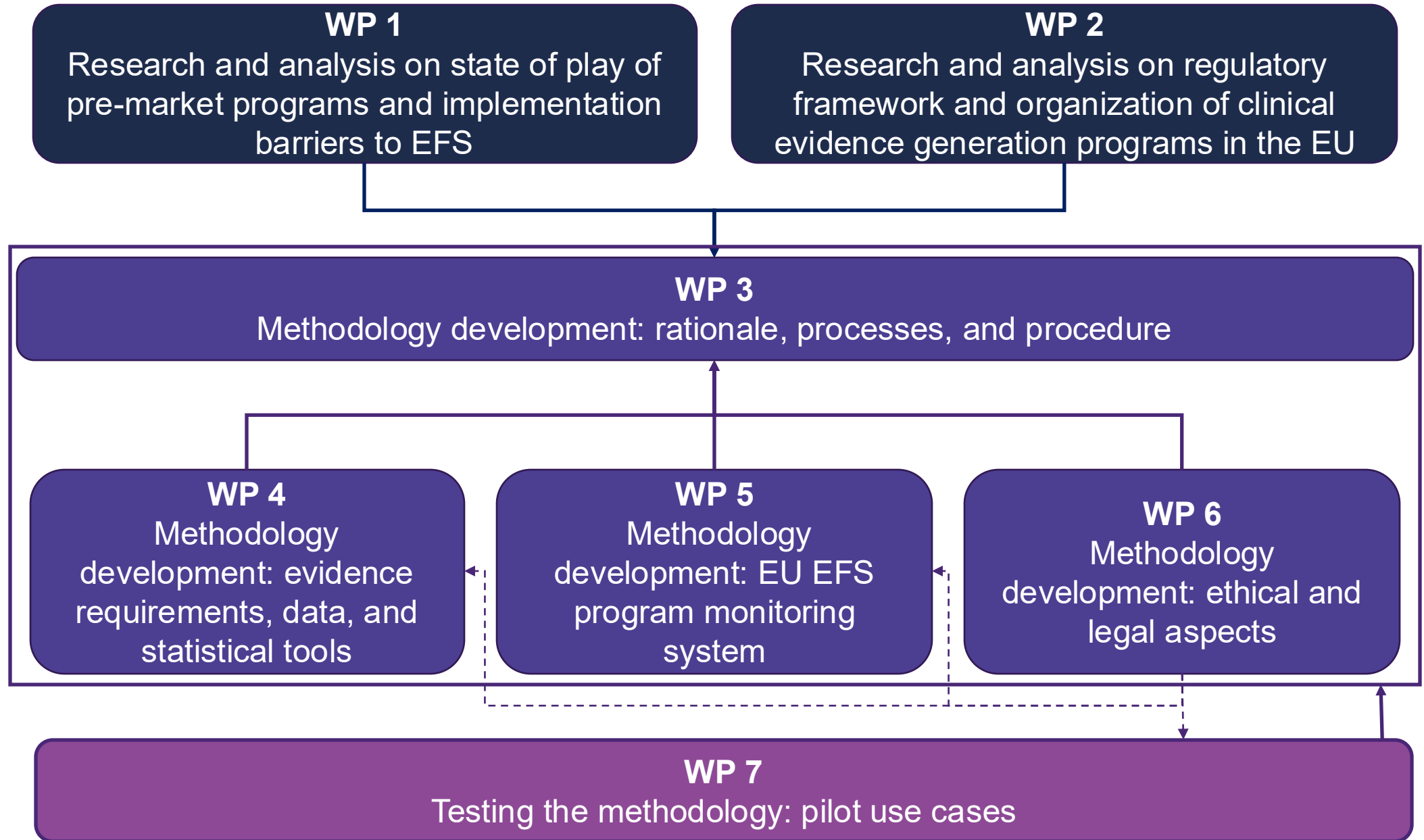
WP 4
Methodology development: evidence requirements, data, and statistical tools

WP 5
Methodology development: EU EFS program monitoring system

WP 6
Methodology development: ethical and legal aspects

WP 7
Testing the methodology: pilot use cases

WP 8
Web portal, dissemination, exploitation, and communication





www.heuefs.eu



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Grazie per l'attenzione
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