



EU4MEDTECH

# European Framework for Advanced Medical Technology Evaluation and Follow-up

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Funded by  
the European Union



**EU4MEDTECH**

Call: HORIZON-HLTH-2024-IND-06

A competitive health-related industry (Single stage-2024)

Topic: HORIZON-HLTH-2024-IND-06-08

Type of Action: HORIZON-RIA

(HORIZON Research and Innovation Actions)

Proposal number: 101191683

Proposal acronym: EU4MEDTECH

**European Health and Digital Executive Agency (HADEA)**



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10 država



14 partnera



>45 članova





MEFST tim

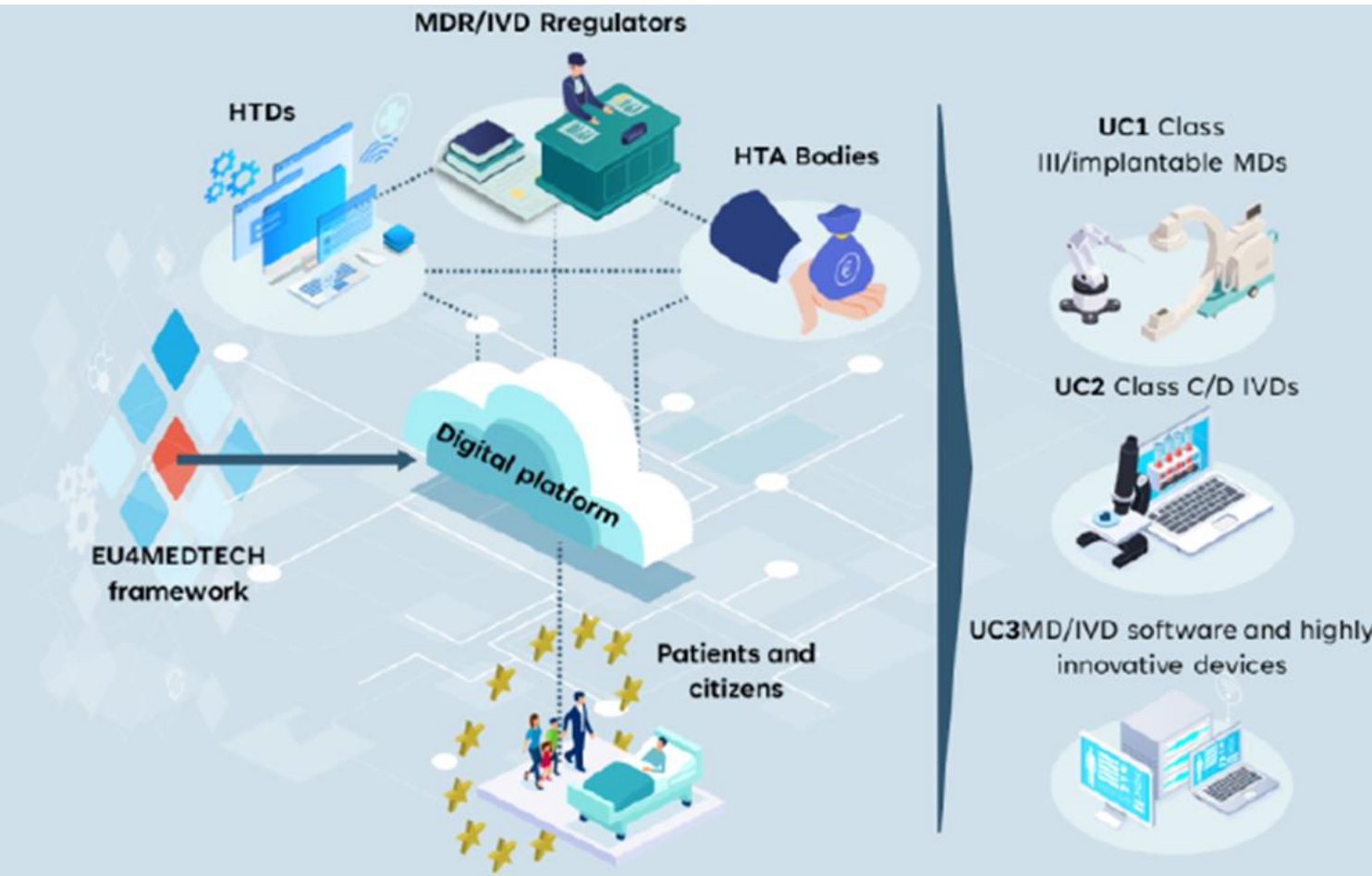
# Cilj projekta

- Su-kreirati i validirati EU4MEDTECH okvir:

*sveobuhvatan skup metodoloških pristupa, standardiziranih modela i višedomenskih kriterija za stvaranje i procjenu kliničkih i izvedbenih dokaza za visokorizične, inovativne medicinske uređaje i in vitro dijagnostičke medicinske uređaje u fazama prije i nakon stavljanja na tržište*



# Konzept projekta



## Main Results

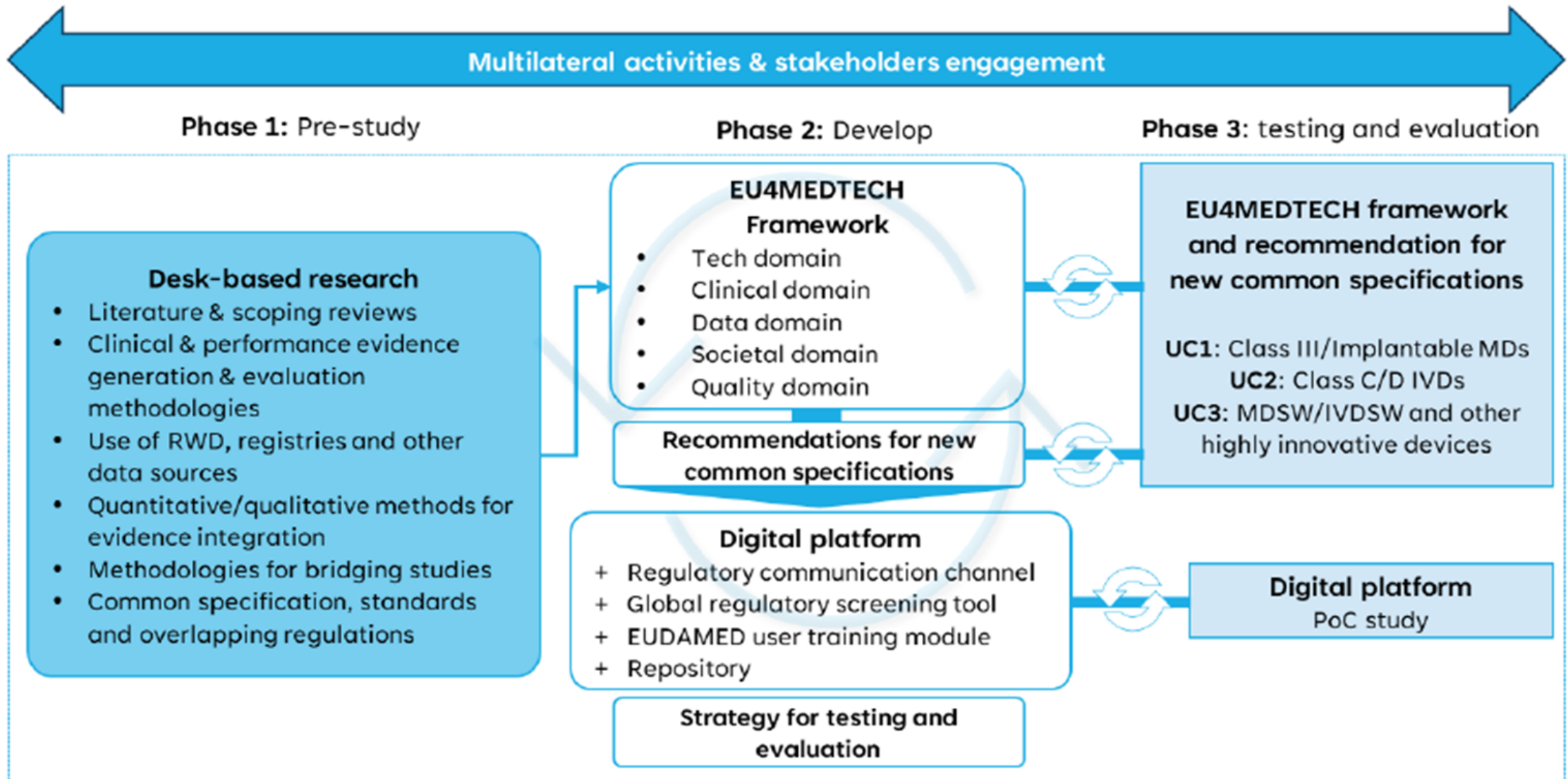
1. EU4MEDTECH framework
2. Standardised assessment models and processes for high-risk, innovative IVDs and MDs
3. Harmonisation of clinical evidence generation/evaluation in pre/post-market
4. Recommendation for new common specifications
5. Digital platform
6. Empowerment of main stakeholder groups:
  - MDR/IVDR regulators
  - HTA regulators
  - HTDs
  - Patients and EU citizens
7. Exploitation plan: sustainability plan for EU4MEDTECH results

## Main impacts

1. Faster market and patient access to MDs and IVDs faster and reimbursement decisions
2. Lessen market withdrawal risks
3. Regulators are empowered with extensive and sound resources for evaluation guidance
4. Enhanced NBs capacity and efficiency
5. MDCs are empowered by better guidance and digital tools for demonstrating life-cycle regulatory compliance
6. Increased competitiveness and sustainability of the EU MedTech industry
7. Increased MedTech value chain efficiency



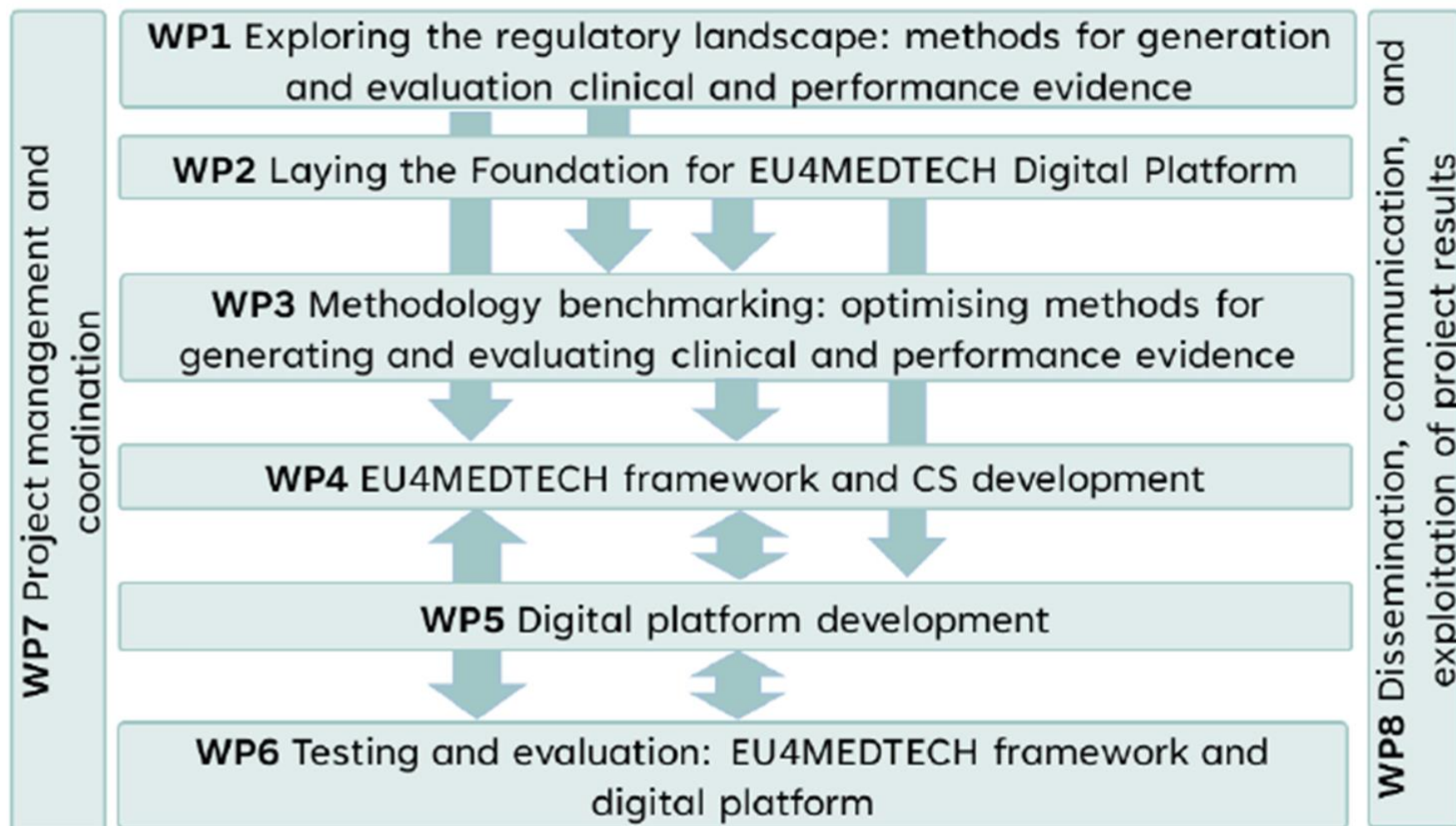
# Metodologija projekta



# Struktura projekta prema radnim skupinama



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# Savjeti – priprema projektne prijave

- Početi rano
  - Čim se objavi poziv
- Početi skromno
  - Mi smo prije ovog projekta, gdje smo koordinatori, “vježbali” na 6 EU projekata kao partneri
- Aktivno tražiti
  - Traženje partnera na EU Funding & Tenders Portal može biti uspješno
- Okupiti dobar tim
  - Međunarodni partneri – umrežavanje
  - Stručna pomoć potrebna za velike projekte

# Savjeti – nakon početka projekta

- Dobro organizirati kick-off
  - Upoznavanje partnera je jako važno
- Koordinator – držati sve pod kontrolom
  - Redoviti sastanci i komunikacija s partnerima
  - Provjeriti imaju li partneri dobru komunikaciju prema nacionalnim tijelima za pitanja vezana uz nacionalnu legislativu
- Što prije potpisati konzorcijski ugovor
  - Početi raditi na njemu odman nakon prihvaćanja projekta
- Dobar tim
  - Znanstveni
  - Administrativni



# Savjet za kraj

- Nije teško
- I na neuspjelim pokušajima se nauči