

Annex 7 – Call for Start-up driven Innovation projects summary

Type of Innovation projects	Facilitating the uptake of Digital Medical Devices & Diagnostics	Harnessing the full potential of health data for Innovation	Service Quality Assessment Innovation projects
Definition	Collaborative start-up driven project Consortia that focus on validating, certification, and introduction to the market of patient-centred innovative Digital Medical Devices solutions and innovations.	Collaborative start-up driven project consortia that focus on validating technologies and building sustainable business models through exploiting existing health registries and biobanks, speeding up clinical trial development and bringing the new innovation developed in the project to the market.	Collaborative start-up driven projects that aim to promote the market uptake of innovative products and services of added value for patients, by assessing the quality of the healthcare service improvement, to generate sufficient evidence to convince payors to reimburse based on value.
Goal	Launch innovative patient centred Digital Medical Devices into the market	Unleash the full potential of health data by exploring the secondary use of data for the development of innovative technologies or solutions that deliver outcomes that matter to patients	Build more resilient healthcare systems that work based on value, not on volume.
Duration	Max 24 months years (may be shorter)		Max 2,5 years (may be shorter) until 31 December 2025 at latest
Indicative grant amount per project	Max 1.5M€ Grant for the EIT Funded Activity (EFA), with max 850k€ Grant per year The grant allocated for start-up must be included in the range [300k€-500k€]		Max 2M€ Grant for the EIT Funded Activity (EFA), with max 850k€ Grant per year. The grant allocated for start-up must be included in the range [300k€-500k€]
Co-funding request	Minimum co-funding level of 30% of EIT Funded Activity (EFA) costs (70% maximum EIT Grant reimbursement of EFA).		
Rules of participation	<p>At Short Proposal stage At least two entities must be involved.</p> <p>At full proposal stage</p> <ul style="list-style-type: none"> At least 50% of the project entities must be EIT Health registered members at the full proposal submission stage. Involvement of industry, healthcare provider and other stakeholders from a minimum of two countries from two different Regional Innovation Hubs. A dossier for the relevant ethics committee approvals to facilitate clinical study submitted and approval to commence study foreseen before project start (for 		

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	multicentric studies, ethics committee approval in place for at least one centre before project start).		
	N/A	At Full Proposal stage: Relevant privileges to access health registry or biobank (to facilitate health registry- or biobank-based clinical study) in place before project start.	At Short Proposal Stage The participants must come from at least two different countries where the clinical partners should be already identified.
Partnership specificities	NA		Two healthcare providers and two payors from the same country as the healthcare provider: one should provide the healthcare services that the other will purchase a Partner taking care of the IT platform integration a commercialising entity taking care of the replicability of the approach in third countries and beyond a Partner with health economics expertise capable to support the development of the required evidence.
		<ul style="list-style-type: none"> • The start-up is at the core of the project – without the start-up, there is no Innovation project. • Start-up is a for-profit SME according to the EU definition – an enterprise which employs fewer than 250 persons and which has an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro. • Be legally incorporated and established in one of the EU Member States or Horizon Europe associated countries. Be incorporated on/after 1st January 2013 and before the submission deadline. • Have at least 2 paid FTEs working in a start-up at the time of submission. • Have a CEO working full-time in a start-up at the time of submission. 	
Supporting Framework	CIMIT Innovation maturity Levels (IMLs) Milestones Framework		HVC Implementation Framework (From “Handbook for Pioneers” report)
Project maturity	Solution or technology maturity level between IML5 (Proof of Value), and IML6 (Initial Clinical Trials) as defined by the CIMIT Maturity Innovation Cycle for Healthcare and Life Sciences, at proposal submission.		The technology to be used should be readily available, in the market, if needed with CE mark granted. Only platform integration developments to

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	The project should achieve advance through IML7 (Validation of Solution) and IML8 (Approval & Launch) within project timeframe.		capture/incorporate/analyse patient outcomes into the IT systems are envisioned.
Impact	Critical milestones for each year (link to the Milestones Framework). Reaching regulatory approval and market launch maximum 1 year after the end of the project.		Critical implementation milestones for each year, plus number of patients that benefitted from the solution. Year 3 focus on large scale implementation (a different region/country from where the test/pilot took place)
Grant spent on technology development	Yes	Yes	No. Only platform integration developments to capture/incorporate/analyse patient outcomes into the IT systems are envisioned.
Commercial agent	Technology provider/ start-up, part of the consortium Every innovation activity should have a clear commercialisation strategy		
Financial return to EIT Health	To be chosen by the consortium at Short Proposal stage: <ul style="list-style-type: none"> Grant for option Financial backflow If consortium chooses backflow model, the start-up will be requested to apply for membership to the EIT Health association, and pay the member-type appropriate membership fee, in line with membership requirements for non-EIT Health partner organisations. Exceptions for Grant requests less than EUR 50,000 per calendar year apply. Changing the chosen return model will not be permitted in subsequent stages of the application and selection process		
KPIs (Mandatory)	<ul style="list-style-type: none"> KIC13: Number of citizens/patients that benefitted from solutions developed or implemented in KAVAs At least one customised KPI linked to Patient Reported Outcome Measure (PROM) EITHE02.4: Innovations launched on the market with a sales revenue of at least 10 000 EUR documented; to be reported during the KAVA duration or within 1 year after completion. Innovations include new or significantly improved products (goods or services) and processes sold.		<ul style="list-style-type: none"> At least one customised KPI linked to Process Outcomes Measure At least one customised KPI linked to Clinical Outcomes Measure EITHE02.1: Innovations launched on the market, or EITHE02.4: Innovations launched on the market with a sales revenue of at least 10 000 EUR documented; to be reported during the KAVA duration or within 1 year after completion. Innovations include new or significantly



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			improved products (goods or services) sold.