

# Annex 8 – Call for Fast Track Start-Up driven Innovation projects (DiGinnovation)

Type of Innovation projects	Fast Track Start-Up Driven Innovation Project (DiGinnovation)
<b>Definition</b>	DiGinnovation selects top digital health start-ups/scale-ups and links them with international entities to create a consortium that will improve Healthcare Systems by accelerating the uptake of digital health apps by healthcare professionals and patients while ease the reimbursement process
<b>Goal</b>	Receive reimbursement for innovative patient-centered Digital Medical Devices and launch these innovations on the market
<b>Duration</b>	Max 9 months
<b>Indicative grant amount per project</b>	Max 350k€ Grant for the EIT Funded Activity (EFA) The grant allocated for start-up must be included in the range [150k€ - 350k€]. Start-up may receive the full Grant of 350k€ provided additional partners part of the project bring co-funding in line with co-funding requirements.
<b>Co-funding request</b>	Minimum co-funding level of 30% of EIT Funded Activity (EFA) costs (70% maximum EIT Grant reimbursement of EFA).
<b>Rules of participation</b>	<p><b>At Short Proposal stage</b> One participant ONLY – the start-up.</p> <p><b>At full proposal stage</b></p> <ul style="list-style-type: none"> <li>• At least two project partners must be involved (minimum one must be an EIT Health member).</li> <li>• At least 50% of the project entities must be EIT Health registered members at the full proposal submission stage.</li> <li>• The participants must come from at least two different countries from two different Regional Innovation Hubs.</li> <li>• A dossier for the relevant ethics committee approvals to facilitate clinical study submitted and approval to commence study foreseen before project start (for multicentric studies, ethics committee approval in place for at least one centre before project start).</li> </ul>
<b>Partnership specificities</b>	<ul style="list-style-type: none"> <li>• The start-up is at the core of the project – without the start-up, there is no Innovation project.</li> <li>• 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.</li> <li>• 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.</li> <li>• Have at least 2 paid FTEs working in a start-up at the time of submission.</li> <li>• Have a CEO working full-time in a start-up at the time of submission.</li> </ul>

	<ul style="list-style-type: none"> <li>• Start-up applying for at least 150k€ EIT Health grant.</li> <li>• The start-up's DMD solution must be already CE-marked and classified as I-IIa or IIb in case of France as targeted market.</li> <li>• The start-up's DMD solution must meet the requirements for reimbursable applications in the targeted country.</li> </ul>
<b>Supporting Framework</b>	<a href="#">CIMIT Innovation maturity Levels (IMLs)</a> <a href="#">Milestones Framework</a>
<b>Project maturity</b>	Solution or technology maturity level IML7 (Validation of Solution) and IML8 (Approval & Launch) with the aim to move to reimbursement and IML9 (Clinical Use) by maximum 1 year following the end of the project
<b>Impact</b>	Critical milestones for each year (link to the Milestones Framework). Reaching market and reimbursement by maximum 1 year after the end of the project.
<b>Grant spent on technology development</b>	No
<b>Commercial agent</b>	Start-up/scale-up applicant Every innovation activity should have a clear commercialisation strategy
<b>Financial return to EIT Health</b>	<p>To be chosen by the consortium at Short Proposal stage:</p> <ul style="list-style-type: none"> <li>• Grant for option</li> <li>• Financial backflow</li> </ul> <p>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.</p>
<b>KPIs (Mandatory)</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• KIC13: Number of citizens/patients that benefitted from solutions developed or implemented in KAVAs</li> <li>• At least one customised KPI linked to Patient Reported Outcome Measure (PROM)</li> </ul>