eHealth HUB Services



Regulatory Guidance

REGULATORY AND REIMBURSEMENT GUIDANCE FOR eHEALTH SMEs

Obtaining CE certification and reimbursement for innovative medical devices are crucial challenges that have to be met by digital health SMEs. **eHealth Hub Regulatory Network** helps European eHealth SMEs to be compliant with regulatory requirements and develop reimbursement strategies across the EU. Through a network of European experts in medical device regulation and reimbursement, the service supports SMEs in obtaining market authorization and market access. Regulatory service is not free of charge: SMEs will negotiate the conditions with the regulatory service provider.

AN OPPORTUNITY NOT TO BE MISSED

The eHealth Hub Regulatory Network offers considerable benefits to both eHealth SMEs asking for a regulatory service as well as consultancies willing to become nodes of the network.

SMEs will be enabled to:

- overcome challenges in CE certification and reimbursement;
- develop and commercialize new medical devices in various European countries.

Regulatory and reimbursement service providers, will be enabled to:

- be a part of a **pioneer sixty nodes** of the European eHealth Hub Regulatory network specialized on the fast-growing digital health sector;
- get direct acces to more than 700 European eHealth SMEs, with a view to increase their EUwide visibility and customer base.

IS REGULATORY GUIDANCE FOR YOU?

The eHealth Hub Regulatory Network is designed to offer tailored services to any eHealth SME looking for regulatory and reimbursement guidance. The Network is open to those regulatory and reimbursement consultancies with experience on EU and national regulatory requirements and/or reimbursement strategies for medical devices, in particular in combination with medical information systems.

WANT TO BECOME A REGULATORY-REIMBURSEMENT NODE?

The eHealth Hub Regulatory and reimbursement network is open to all regulatory and reimbursement specialists in Europe, helping eHealth startups. For more information, contact Nicole Häusler (n.haeusler@ engage-ventures.com) or Björn Hackbarth (b.hackbarth@engage-ventures.com). To become part of the network you can "Register" directly through eHealth Hub website (Services Section).

ACTIVITIES - EVENTS

The eHealth Hub Regulatory Network is keen to provide European eHealth SMEs with continuous service support during eHealth Hub project lifetime and beyond. Regulatory awareness workshops will be held within major eHealth events at stage in Europe, starting from the Health 2.0 2017, Barcelona.

Contact us: info@ehealth-hub.eu | www.ehealth-hub.eu | 🕥 👔 | Learn more about eHealth Hub services









eHealth Hub is a cross-border initiative, exclusively focused on the digital health vertical. Our mission is to provide long-term support to the ecosystem stakeholders and address all the key challenges faced by European SMEs in this space: fine-tuning a business model, securing investments, engaging the demand-side and accelerating commercialization, getting legal and regulatory guidance to develop solutions in compliance with a multi-layer complex framework.

