

Market access & reimbursement for health apps

Differences and similarities between the French and German
approaches

September 24th 2020

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&

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1 MARs Market Access & Pricing Strategy GmbH, Germany

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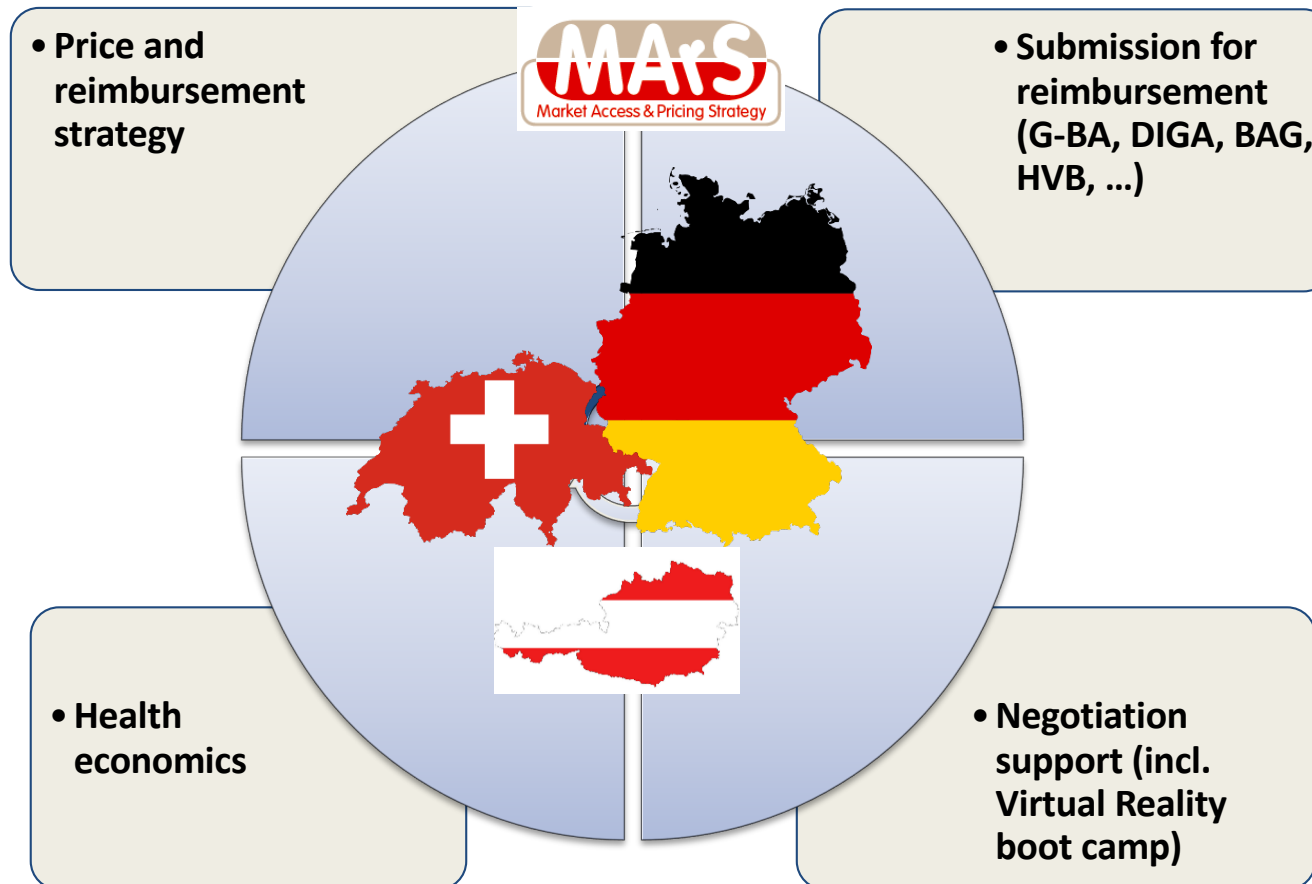
3 University of Applied Sciences Ravensburg-Weingarten, Germany

4 Nextep SAS, France

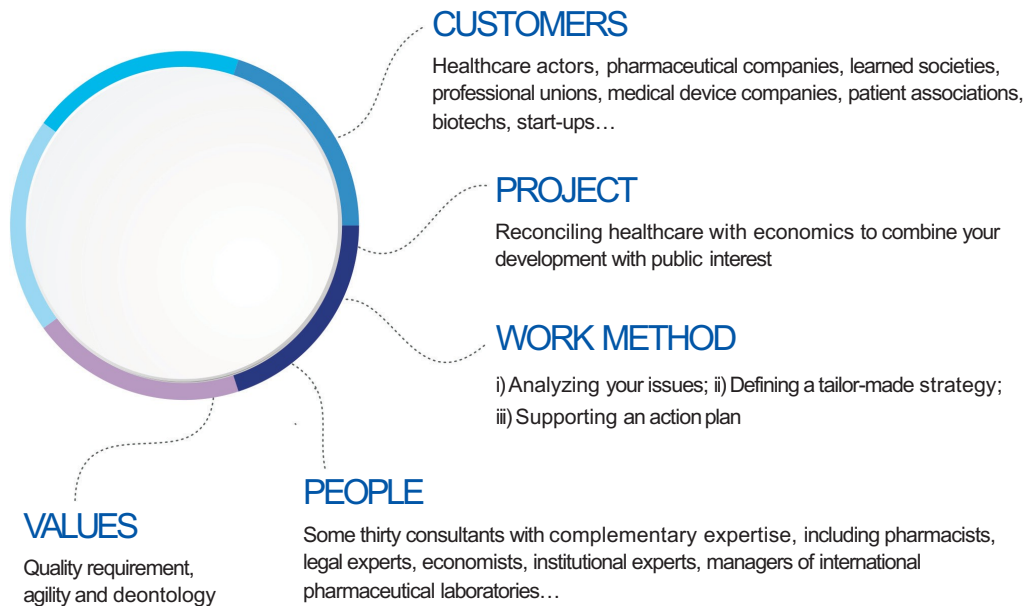
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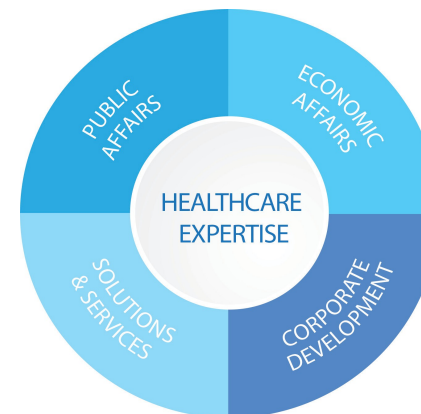
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Proposing new value-based approaches and developing innovative services for patients



Allowing patients to have quicker access to health products by promoting innovation and taking into account the budgetary impact for the community

Seeking answers to the strategic issues faced by decision-makers with regard to the future of their business model

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Business Benefits

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LONG-ESTABLISHED RELATIONSHIPS
WITH NATIONAL STAKEHOLDERS
AND HTA BODIES

- A **“Think global, act local” philosophy** across key healthcare markets ensuring an EU wide designed strategy and in-country execution according to local procedures
- An **integrated governance** allowing for close coordination when implementing cross-country strategies

- Over 100 consultants and decades of cumulated experience obtained from over 300 projects every year
- Tailor-made solutions to address global market access and public affairs challenges
- Ability to choose one point of contact from any of our local headquarters or work with partner firms other than the founding members when requested

- In-depth understanding of local environments, health markets and political dynamics
- Local offices, local consultants, local language
- Long-established relationships with national stakeholders and HTA bodies

Questions welcome!



- Feel free to ask questions. After the presentation, we will have time for your questions.
- Use either the Zoom chat function or the Q&A function to raise your questions or comments.
- As always, slides will be provided afterwards and the video will be published on our website.



Webinar

EU-HTA to come?

How could such a system be implemented
in Europe and the different health care markets.



Market Access &
Pricing Strategy GmbH



Dr. Stefan Walzer
Speaker



Lutz Vollmer
Moderator

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27.08.2020
9pm CET /
12am PT



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[Covid-19 pushes digitalization in health care \(26.05.2020\)](#)

[The economic impact of Covid-19 in Germany \(23.04.2020\)](#)

 100 day health care cost of Covid19 in G...



100 day health care cost of Covid19 in Germany

Webinar by

Lutz Vollmer, Health Economist
Dr. Stefan Walzer, General Manager
MARs Market Access & Pricing Strategy GmbH

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The idea by German health politicians...

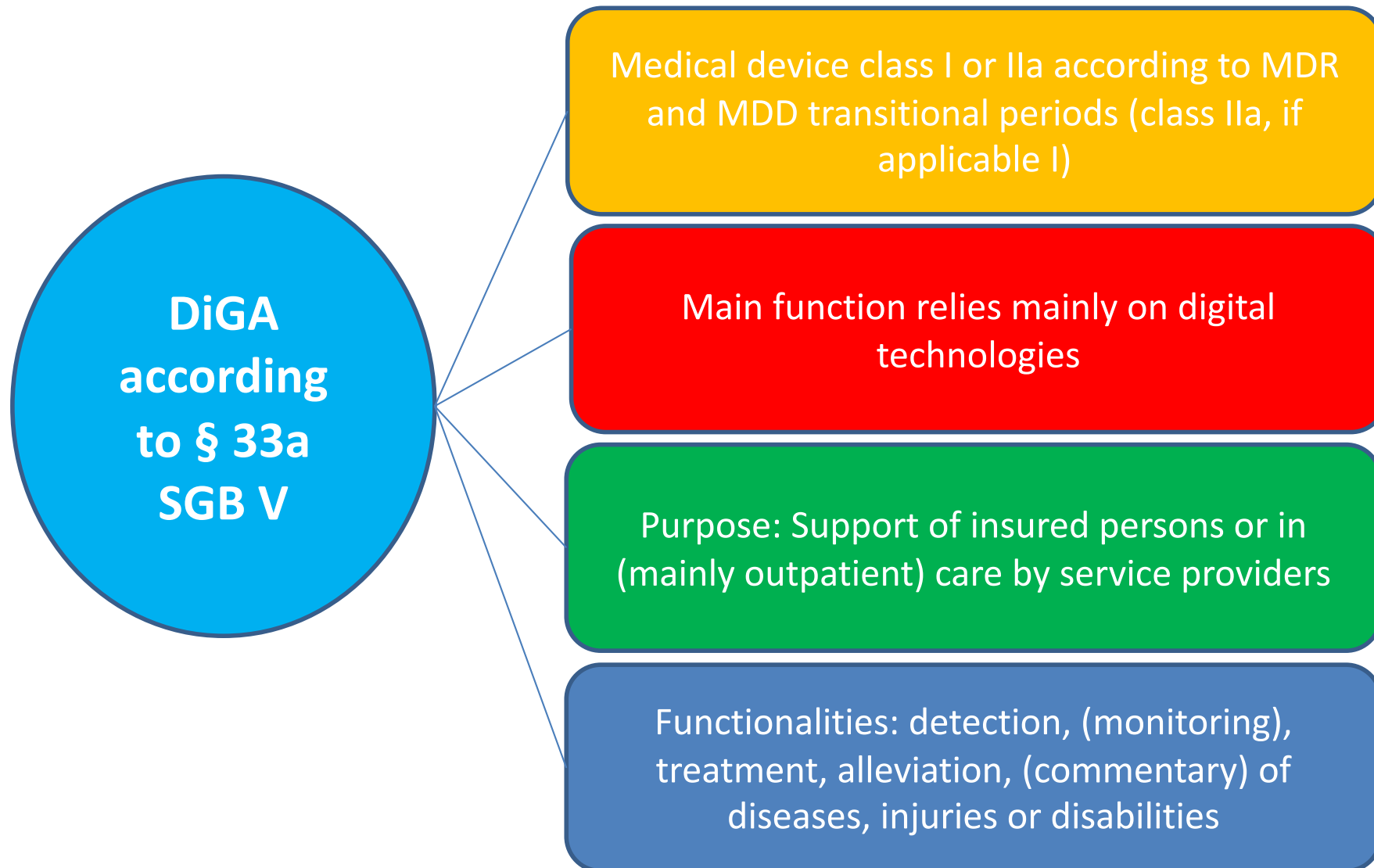


Driving the digital transformation of Germany's healthcare system for the good of patients

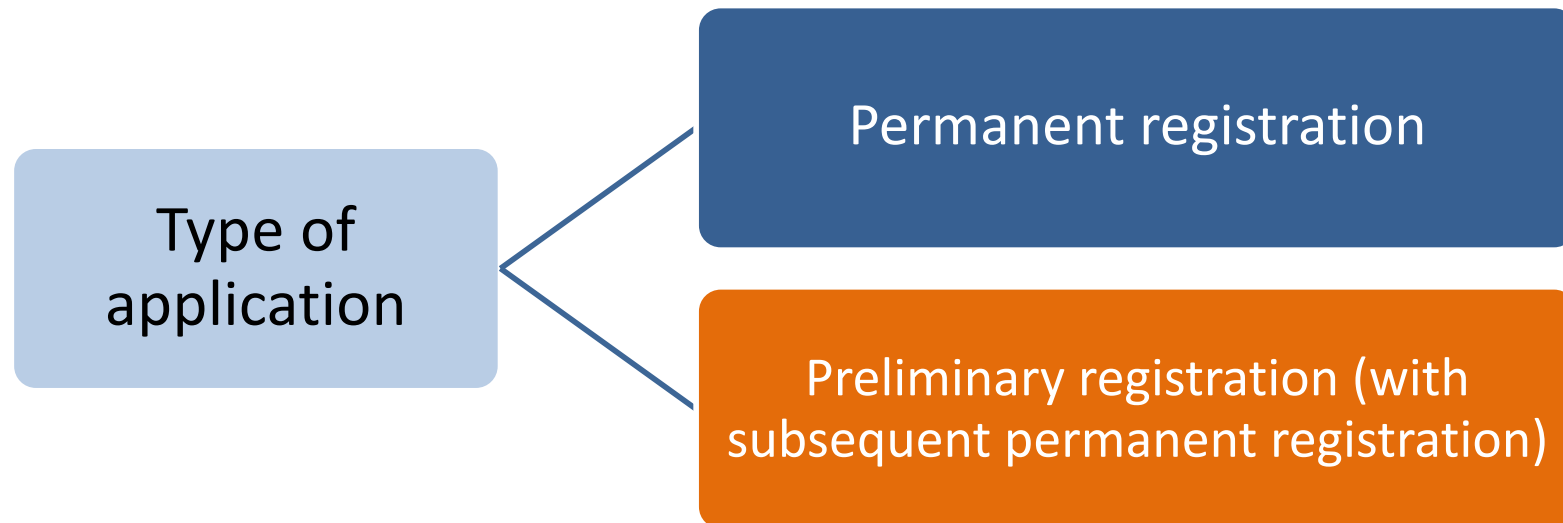
**The Act to Improve Healthcare Provision through Digitalisation and Innovation
(Digital Healthcare Act – DVG)**

Apps on prescription, easy use of online video consultations and access to a secure healthcare data network for treatment everywhere – all achievements of the “Act to Improve Healthcare Provision through Digitalisation and Innovation” (Digital Healthcare Act – DVG), which was approved on 7 November 2019 by the Bundestag and adopted on 29 November 2019 by the Bundesrat.

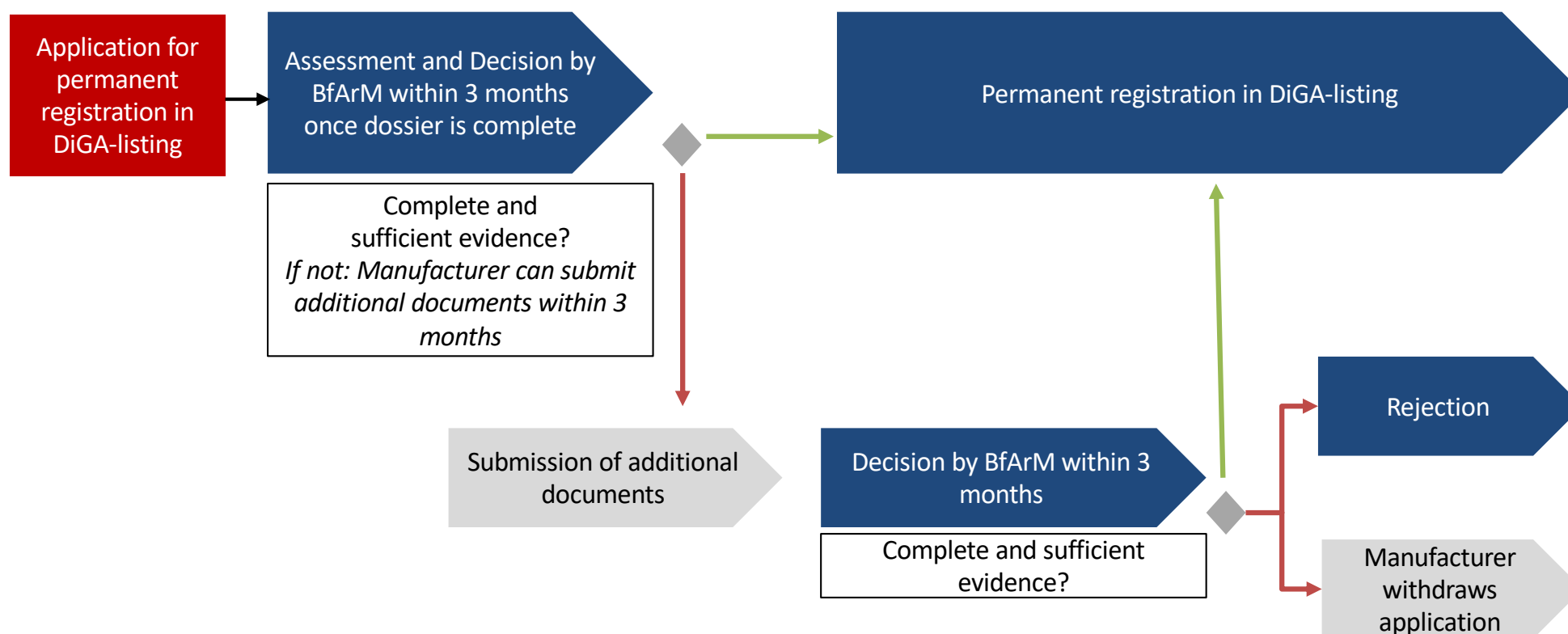
Definition: Digital Health Application („DiGA“)



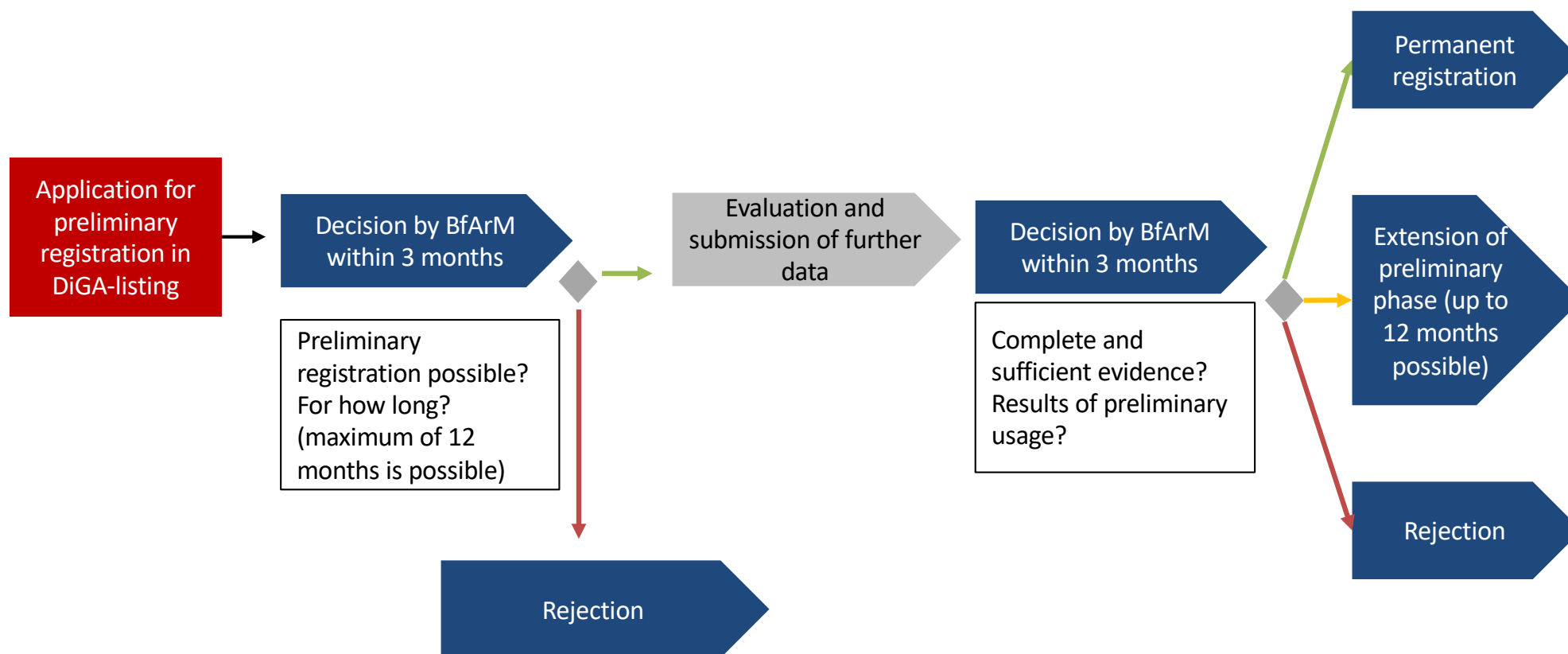
Types of DiGA-listings



Process of permanent registration in DiGA-listing



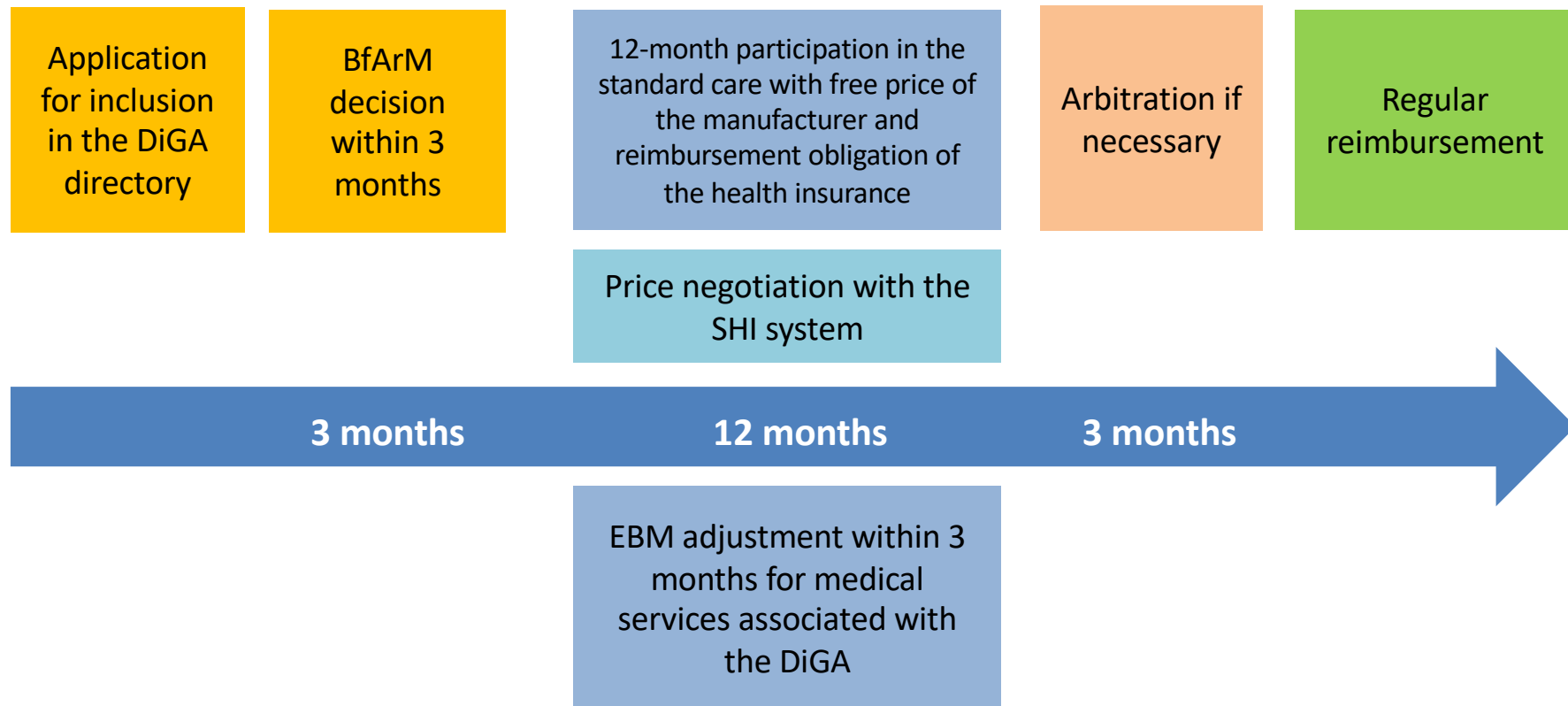
Process of preliminary registration in DiGA-listing



Legend

◆ Decision requiring binding criteria

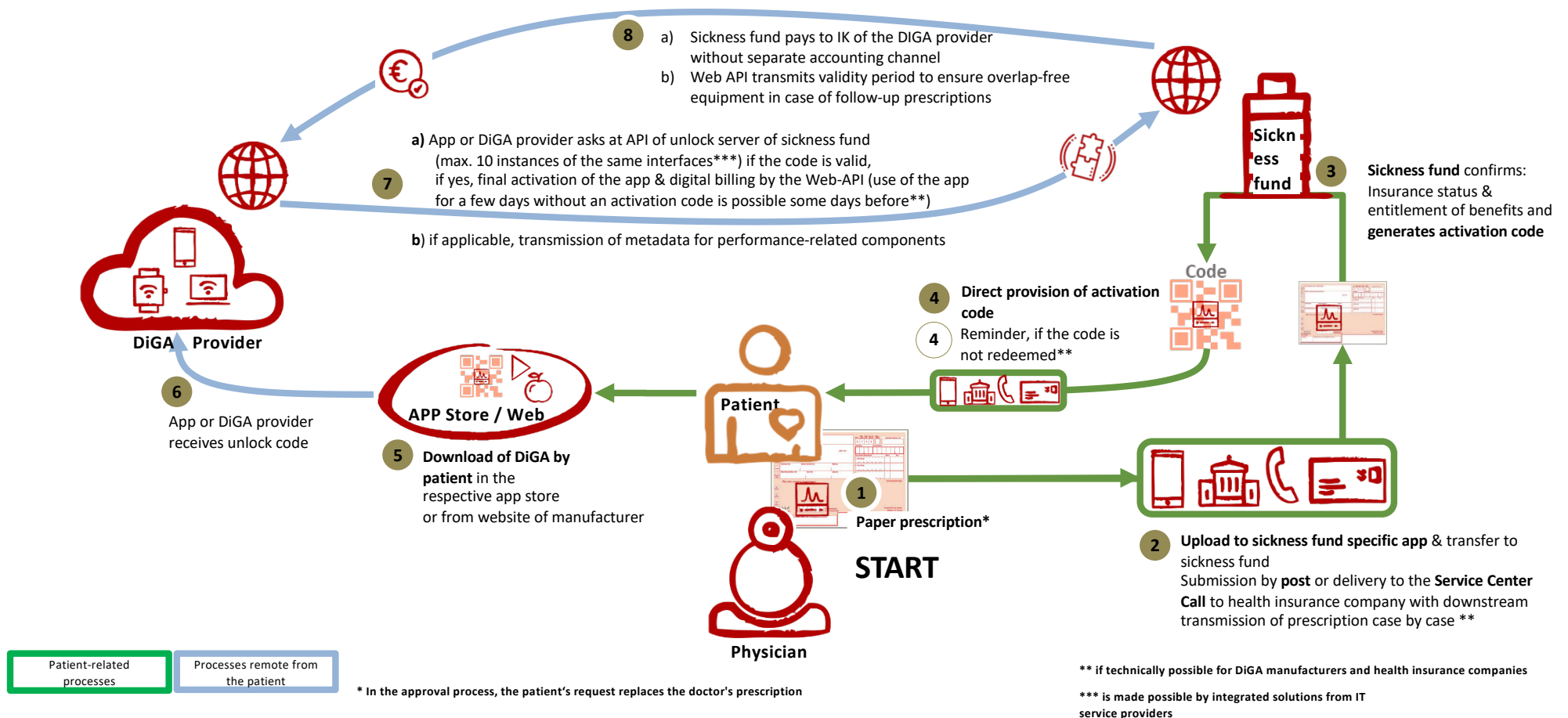
Time to reimbursement



Consensus process & launch configuration

(status: not yet finally agreed – as of September 22)

DRAFT



My Health2022 Bill (pre Covid)



Many relevant provisions ...

New ways to pay / reimburse (by episode rather than activity) .. **requiring generating and analyzing data**

Increased empowerment of Regions ... **favoring local experiments**

Hospital regrouping .. **triggering Information Systems upgrade**

Increased access to public health data .. **with creation of a National Agency, the Health Data Hub**

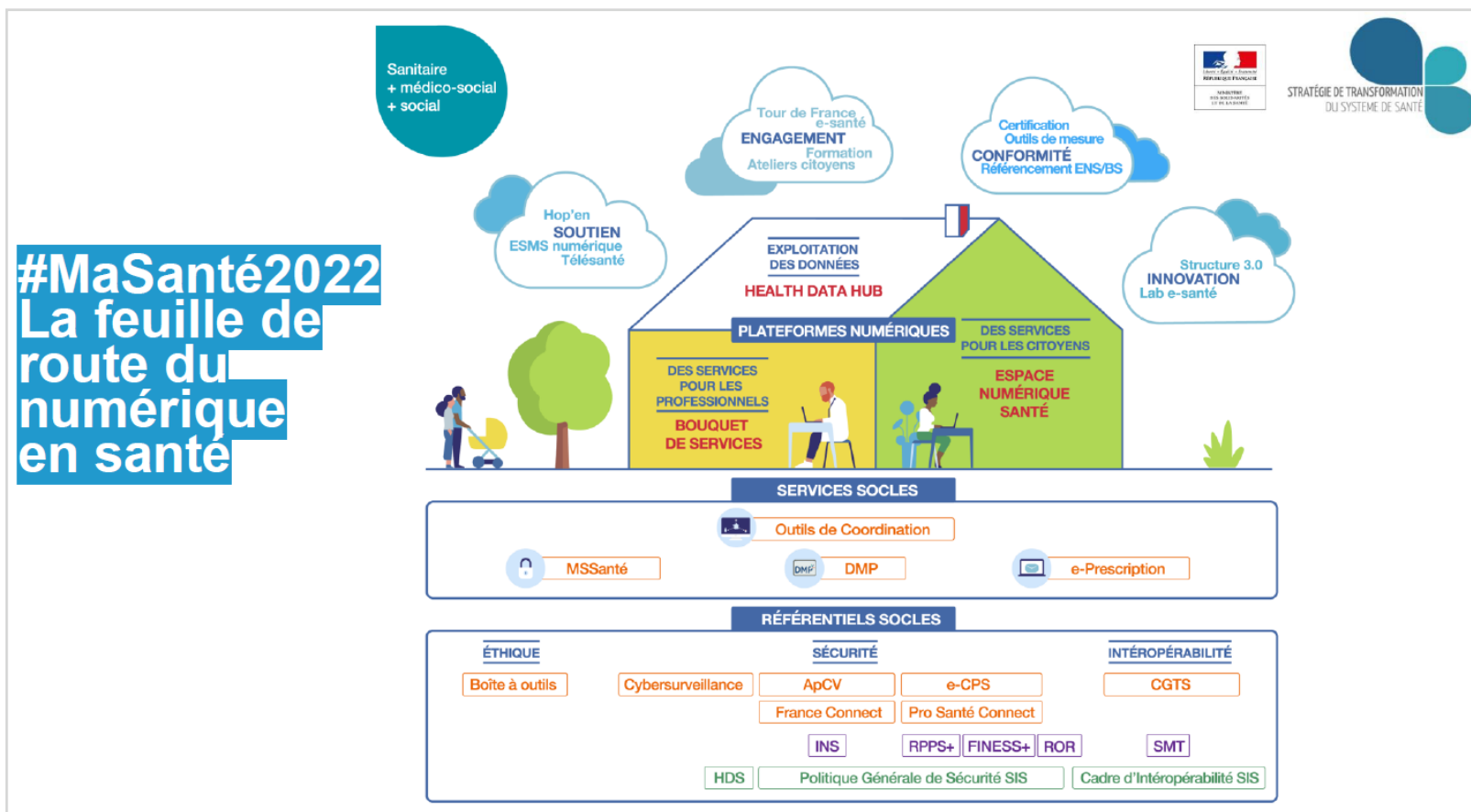
Incentives for HCPs for telemedicine & e-prescription ... **removing major barrier for adoption**

Delegation of tasks to nurses, medical assistants ... **requiring tracking of data**

Increased role for patients & their representatives ... **triggering development of P.R.O.M. Systems**

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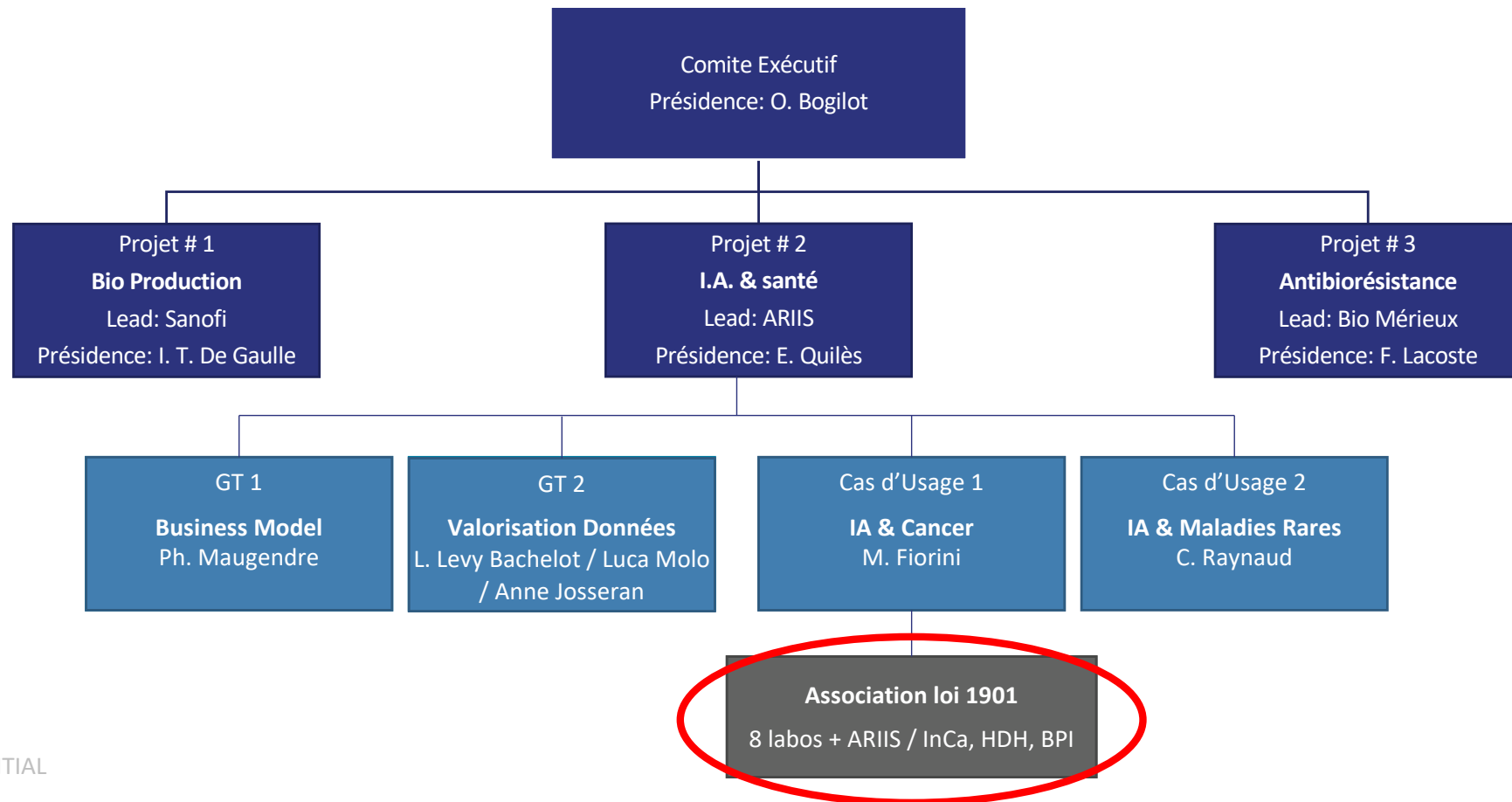
Status Report for Digital Health Roadmap (Dec 2019 – PreCovid)



COVID-19

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Illustration of Capability Creation / Enhancement : AI & Cancer Project in CSF



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Illustration of a Stand Alone Therapeutics or Services

Diabeloop

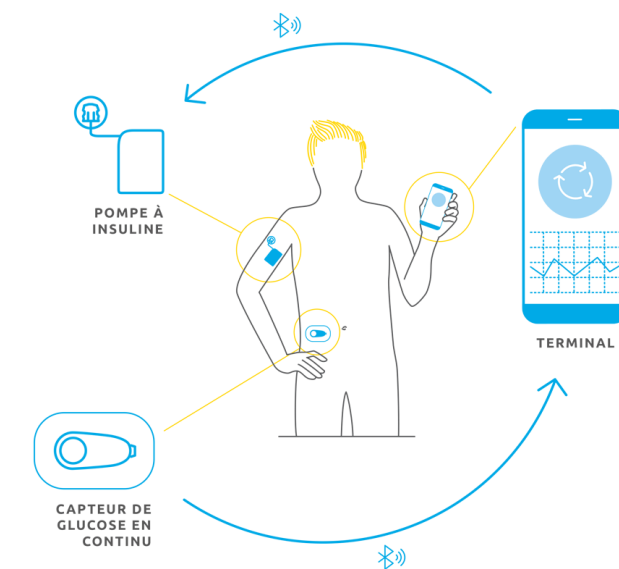
For the first time **the HAS recommended a 3- year reimbursement period** for the DBLG1 semi-closed loop insulin delivery system from the French company **Diabeloop**.¹

This **"artificial pancreas"** system combines an insulin pump, a blood glucose sensor and a self-learning algorithm that calculates the insulin doses to be administered based on continuous blood glucose measurement and information entered by the patient, and automatically controls the delivery of insulin by the pump.

The comparators considered for HAS evaluation were "open-loop" systems that include an insulin pump and an independently operating interstitial glucose sensor.

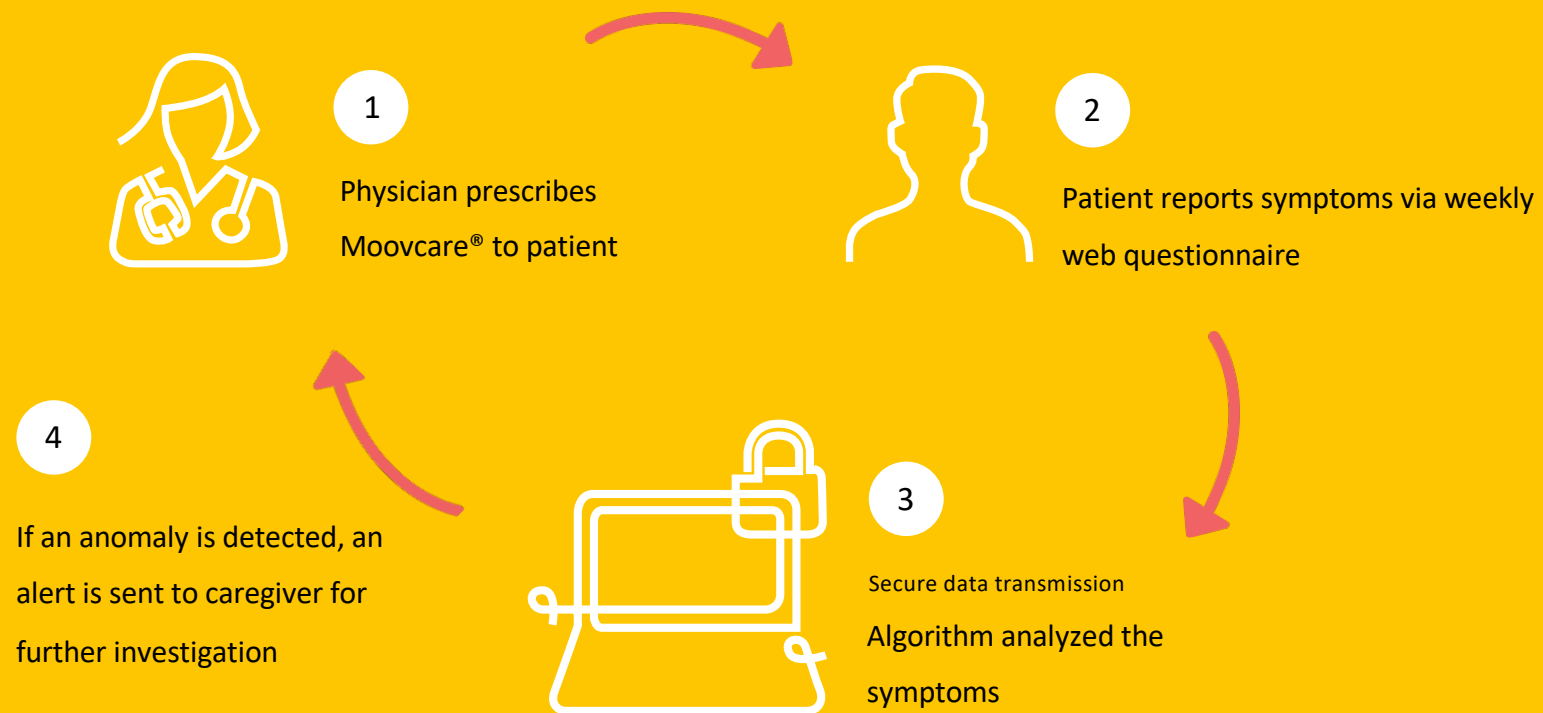
The product was given an **ASA III & a "sufficient" SA**

Cnedimts made the renewal of the DBLG1 listing conditional on ***"the completion of a comprehensive prospective study on all patients using the system"***.



© Diabeloop 2019

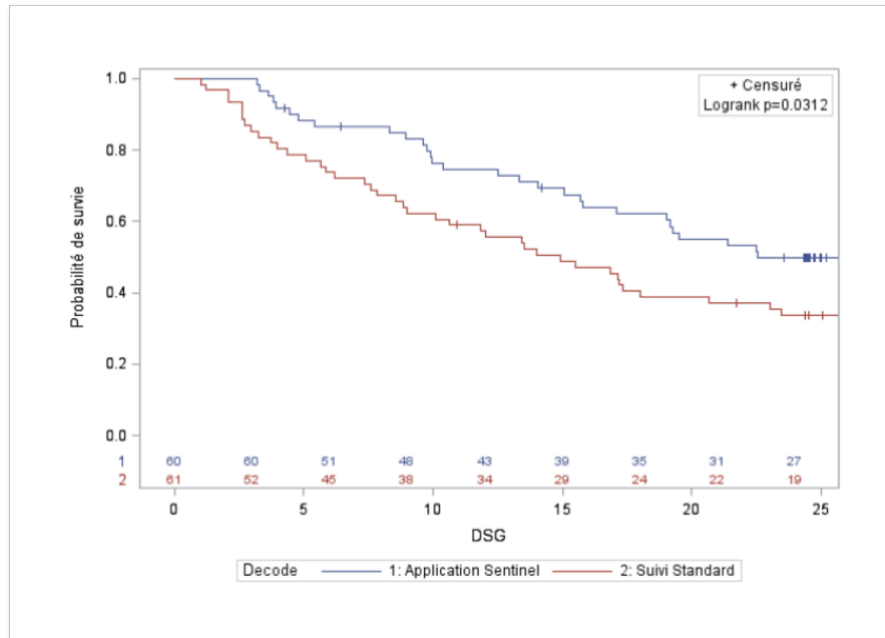
Moovcare Workflow



Moovcare Impact on Overall Survival



**First Digital Therapeutics
Reimbursed by French National
Health Fund**



Significant improvement in overall survival of 7.6 months in the SENTINEL group compared with the standard group: median survival of 22.5 months [17.0 - NV] vs 14.9 months [8.9 - 20.6] ($p = 0.0312$)

ASCO®

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Two-Year Survival Comparing Web-Based Symptom Monitoring vs Routine Surveillance Following Treatment for Lung Cancer

Do not forget your questions!



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Conclusions: Different pathways in Germany and France – but both are getting ready for the future...

Germany has a dedicated new reimbursement pathway for DiGA including “experimental coverage”

France has adopted its existing reimbursement process to be applicable also for digital health solutions



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Please visit our website www.marketaccess-pricingstrategy.de
where you will find more information.

In case of questions please contact me directly:

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Dr. Stefan Walzer
Speaker



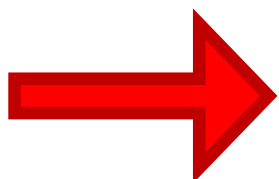
Roman Spelsberg
Speaker



Lutz Vollmer
Moderator

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