Questions and Answers

What are the reimbursement pathways for innovative digital health technologies?

Question: Can I launch my product to consumers through the app store or play store first and request insurance funding later?

VCLS Answer: Yes, it is certainly possible, however, we think the caveat here is that it might be important to consider that a version you can freely commercialise may not be entirely the same version that you can propose for reimbursement. For instance, some elements such as advertisement could not necessarily go into a reimbursable version in all countries. In general, you can launch your product to consumers before reimbursement and this is a good way to collect additional data that can be used for your reimbursement and funding request and as general feedback on your product.

Looking at the US market, the opportunity is there, however, it is also incumbent on the company or organisation to show the medical purpose or clinical purpose behind a product, as well as value, - especially to the US payers - which is very important. Yes, the opportunity is there with a caveat that you must show clinical efficacy or a medical purpose once the product is in line to be reimbursed.

Question: I have heard some of the payers in Europe require cost-effectiveness modelling to make funding decisions for medical devices. How do I know if I need to prepare such a model?

VCLS Answer: Yes, certain payers - and we often think of the UK when it comes to cost-effectiveness model – will require modelling as part of their funding assessment. It is something to investigate whilst you are looking at your access pathways to really understand what type of evidence is required for a funding request submission. In countries such as the UK, cost-effectiveness is a more standard requirement, but it might be optional in other markets or only required under certain circumstances in other countries (e.g. France). Depending on your product, you may or may not need the economic modelling – there are also many countries that require budget impact models. Therefore, having the analysis of the markets but also the discussions with the potential payers are extremely useful.

Question: What happens to my reimbursement status if I launch a new product version?

VCLS Answer: The reimbursement status if you introduce a second product or another product will fall under the consideration by CMS and the commercial payers who may or may not require any additional major submission of data and information. However, they will want to understand the product, the clinical evidence supporting that product and the economics support for that product. It does vary from payer to payer if you add an additional product, but by and large the process is to just submit to the payers especially if they have already accepted your first product, the additional material, the additional information regarding the product and the target patient population, perhaps economic end point information or clinical end point

information, but it's just a matter of having those conversations as they will vary from payer to payer.

Question: With respect to France, which regulation (articles) should be followed, are the 180 days realistic? We have heard the timing is much longer, sometimes several years before you get a decision. Is it the standard pathway you are referring to or a specific pathway for MD?

VCLS Answer : The 180 days shown in the slides are what is considered "by the book" and they do not consider any 'clock stops', if there are any questions or additional back and forth between you and the authorities looking for supplements to your dossier or taking longer to negotiate prices. The 180 days is really a best-case scenario, and we know that the typical length of the reimbursement process is rather beyond 200 days. "Several years" though sounds a bit exaggerated for the process itself, but there might be other reasons for the delay to the start of the reimbursement process or funding agreements and this might be linked to the type of access pathway. However, there is no short or easy answer to the questions around the reimbursement pathways. The pathway highlighted in the session was for the reimbursement for technologies that are used in the outpatient setting, but it will depend on your technology if this is the right route.

Question: Should national authorities be approached to discuss what patient outcomes are relevant with respect to future reimbursement procedures? If so how, and when would you recommend proceeding with this early contact?

VCLS Answer: It is a very important aspect of getting your access and reimbursement request right. In several different countries there are now possibilities to engage with payers at an early stage and this can be as early as before your pivotal trials or clinical studies. This way you can already get the payers' input on your trial design and comparators. This is really an opportunity and we would encourage you to take advantage of it, because you have a chance to get your trial design right from the start, plan for the commercial side of your product development and reduce risk of suboptimal or no reimbursement. From the EU side, it is never too early: any concepts, ideas, any study protocol can really be brought to the payers for these early engagements.

From the US perspective, the same is true, it depends in part on how the studies are designed but it's important to actually be able to present them to payers as early as possible, especially with some of the initiatives in the US where that's being encouraged even more: For instance, some of the newer models and programmes including the FDA collaboration with CMS to engage in earlier conversations with payers. There are several different opportunities in the US.

Question: Do you have clarity on how medical device regulations in the UK will be impacted by Brexit? Will you need a separate classification for the UK market?

VCLS Answer: No specific changes in terms of market access are expected. NICE is preparing special provisions for digital health.

As for regulatory aspects, Brexit had as a direct consequence the establishing of a new regulatory route since Jan 1st, 2021 for placing medical devices on the UK market: UKCA marking (to be delivered by UK CAB conformity assessment bodies). CE marking certificates issued by European Economic Area (EEA) based NB (under MDD or MDR) will remain valid for the UK market until June 30th, 2023. Finally, Manufacturers based outside the UK will need to establish a UK Responsible Person.

Question: AI software as a diagnostic tool, a monitoring tool, or a software integrated into a hardware system through a software upgrade? What reimbursement pathways may exist for these scenarios? Can you piggy-back on existing pathways or is it better to develop a new reimbursement pathway for these?

VCLS Answer: This question covers a lot of different technologies and there is no clear answer. In terms of market access, it is important to consider the specific product and find the "right" or "optimum" access route. So, we cannot really answer this question without knowing more about the technologies.

In general, diagnostic software, monitoring software and device-software technologies may face very different access routes and funding pathways, even within one country alone, and then there will be country differences. There are existing pathways for all the above examples across the markets we discussed, but it may not necessarily be one of the reimbursement routes dedicated to digital health and with that there might be some challenges and particularities to anticipate.

Question: In France and Germany, are early dialogues open for digital app at all stages and can we discuss these issues both before clinical trial and before first submission or this is a one-shot interview?

VCLS Answer: In both countries, there are different types of advice sessions for digital technologies offered depending on the stage of development of the product. For early development stages this is to obtain input on the development plan and trial design. Other advice sessions are more targeted to the submission process and requirements and are typically more useful at a later stage of development.
There is continuity in that sense, but these meetings and sessions are formal and access to them may be limited or waiting times can occur. Also keep in mind that the some of these sessions have fees.

Question: Whole service package: how to prepare for changing reimbursement models? meaning - reimbursement time limitations, country limited access (digital health)

VCLS Answer : This was probably already addressed during the webinar after this question was raised, but to highlight some aspects again: Payment models are the most important part and possibly any other business model questions, maybe including reimbursed and out-of-pocket components (e.g., in-app purchases). Designing subscription-based models needs careful consideration and planning, and even more so for outcome-based payment models. All of this should be a coherent package that works for patients, payers and the company offering and further developing the product.

Question: Are HTA bodies in Europe open to have joint meetings with the NB or the competent authority on evidence requirements for CE marking and for reimbursement?

VCLS Answer: Consultations with regulatory bodies (NB, NCA) concerning regulatory clinical data are in VCLS' experience typically performed independently from those dealing with medico-economic clinical evidence for reimbursement purpose with HTA bodies.

Question: Seek reimbursement EE UU - Switzerland (..); UK - US, Asia - which approach is best when not pairing up with GAFA…

VCLS Answer: Very complex question…. It really depends. First consideration would be around regulatory strategy: CE mark and FDA clearance will open doors to many other markets or may even be the first requirement.

Digital health adoption is picking up around the globe – we have not focused on Asia in the webinar, but digital health and reimbursement policies are being implemented there as well. However, your development and launch prioritisation will depend on the overall digital health ecosystem of a country/region and the therapeutic area(s) you are operating in. Many software-based medical devices are much more dependent on language and national care pathways, and different products being marketed in different countries. This means your digital health competition might be harder to identify than to identify medicines being used. Even if this is not the case for your product, you will have to undertake an opportunity and market assessment and your strategy may differ from one product to another.

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