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8 TIPS ON HOW TO ACCELERATE AND DERISK A DTX PROJECT

Developing and implementing a digital health solution in a real-world setting is a daunting task that could require considerable effort, especially when you have a limited experience in the medtech and digital worlds. The pharmaceutical industry has a broad range of expertise, including drug discovery, chemistry development and clinical evaluation, regulatory affairs, and market access. However, the impact of this expertise changes completely when it comes to designing, developing, validating (clinically and technically), and bringing to market a digital health solution. These solutions add value to traditional pharma drug assets by providing a sustainable competitive advantage, improving patient and HCP experience, and integrating smoothly into outcome-based frameworks that are expected to burst in the coming years.

But this is not easy. That is why we put together 8 tips to help you save time and choose the right partner for building a digital therapeutic (DTx).

1. Define a detailed and comprehensive project brief

A complete, well-defined, and shared project brief is essential to move forward at the right pace. To do this, you need to think carefully about the final solution, picture it in the hands of the end users, patients, or HCPs, in a real-world setting. You must identify what the DTx can bring to the patient and which technical components are needed for its implementation. Identifying the need and formulating it in simple terms is necessary to steer the project in the right direction from day one.

2. Have the will to deliver quickly

Picture a feasible project and give yourself the means to do it in a defined timeframe. Several obstacles can put the plan at risk, so anticipating them is essential to deliver a solution quickly. The scope must also be realistic and achievable — the more clinically and technically complex the solution, the longer the timeline.

3. Widen your field of vision

A company that has already developed its own digital therapeutics is aware of how to intervene in the entire DTx value chain:

- **Design:** Medical analysis and patient journey definition;
- **Development:** Risk assessment, human factors engineering, solution architecture, cybersecurity;
- **Regulatory:** Quality system, certifications, standards, submission files, contact with notified bodies in concrete terms, everything in place to de-risk the project;
- **Market access:** Market definition, targeted population, knowledge of healthcare systems, reimbursement framework, price definition;

- **Operational:** Solution maintenance, hosting, data protection;
- **Data collection and analysis:** API, devices/software integration, data analysis infrastructure, reports.

This means your future partner can support you throughout the overall project and will better cope with difficulties, having faced similar obstacles during the development of its own DTx.

4. Commit yourself to the project

Your commitment is key. To make sure that you (the pharma company) and your partner share the same direction, it is important to set up regular meetings to present what has been done and validate each evolution. This saves time because you can follow the evolution and growth of the DTx step by step. It ensures a proper conduct of the project, and anticipates new requests, and changes in direction. It is easier to start from scratch than to start over with something that has already been built and approved.

5. Identify the appropriate regulatory strategy ASAP

Working with a company that has put in place an internal quality system tailored for SaMD development, that knows the regulations in each territory, and has already been confronted by notified bodies is a real time-saving advantage for a number of reasons:

- All employees are trained and are aware of regulatory issues, creating a regulatory culture within the company that's shared by all employees.
- The quality and regulatory documentation is an integral part of the DTx design and development process, thus facilitating the tracking of information and interaction with regulatory bodies.
- An understanding of regulatory bodies and methods for getting a SaMD approved saves time. For example, knowing the criteria for an enforcement discretion submission in the US can save six-to-nine months. In the EU, you can submit a SaMD for the CE Mark without any clinical data if a similar SaMD has already been marked.
- Experience with institutions gives credibility to the partner company and creates trusted relations, as the company is well known by the notified bodies.

Partnering with a company who has its own certified QMS and internal skill set developed over years of experience also means that it can take on the role of legal manufacturer. This enables you to avoid having to set up a quality system that meets the SDLC (Software Development Life Cycle) requirements or manage post-marketing aspects, such as device vigilance or compliance handling, so you can focus on your expertise.

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6. Develop a flawless team spirit

What do a software engineer and a doctor have in common? Or a quality engineer and an IT manager? How about a UX designer and a cybersecurity officer? At first sight, not much. However, within a medtech company, all these functions meet and must work together. It is very important that a collective mindset grows among these departments to operate on projects quicker. Medical affairs teams must be sensitive to development issues, and developers must grasp the clinical needs. A common language must be established so that they can collaborate to grow the project.

7. Let the professionals advise you

Collaborate with an expert company that will support and advise you on both technical and strategic issues. Marketing a DTx is a totally different approach than marketing a drug. Developing a DTx with a specialized partner can be beneficial in terms of time, risk, and costs, while developing a drug does not require the same expertise and skills. These are two distinct worlds with different cultures, codes, and languages. As a result, the collaboration becomes even more relevant when an advising dimension is created between the pharma and the DTx company. This way, the DTx company supports pharma in its digital transformation and saves time by being able to intervene on the entire DTx value chain.

8. Select THE right partner

There are countless medtech, digital health, DTx, ePRO, and SaMD companies to choose from, so selecting the right partner isn't always easy. Some companies are very specific; others more general. Some are a few years old, and others were born at the beginning of the internet bubble. But what must be considered is how well the partner company can meet your needs. This is why it's important to include the project team initially so that the need is well understood to avoid back and forth during the development phase. The more accurate information your partner receives, the better it can estimate the time needed to complete the project in its necessary schedule and scope to minimize frustrations along the way.

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If you have a project to develop or would like to know more, we would love to hear from you..

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