Medical device clinical trials – Just the necessary evil or crucial competitive factor?

A closer look at German medical device startups

Medtech innovations and new medical procedures are key drivers of advances for patient care. But payors continue to sharpen their focus on the economic benefits and the clinical evidence-based proof of those innovations. Since 2010, drugmakers have to undergo an additional procedure according to the German AMNOG law. Now, on European level, guidelines for "Health Technology Assessments" are being developed that will change the re-imbursement framework for medical devices in the future. How do German medtechs, i.e. startups react?

The Research

In 2015, Hitec Consult Market Research (Bad Nauheim, Germany) conducted a series of telephone interviews on behalf of Activoris Medizintechnik GmbH, evaluating the attitude of German medtech companies regarding clinical trials. Of the 435 contacted companies, 28 startups and 14 SMEs answered the questions of the interviewer.

Demographics of the Participants	*Startup*	*SME*
Participants	28	14
Male	71 %	93 %
Age of Organization (Years)	3,5	28
No. of Employees (av.)	7	31
Product on the Market	46 %	100 %

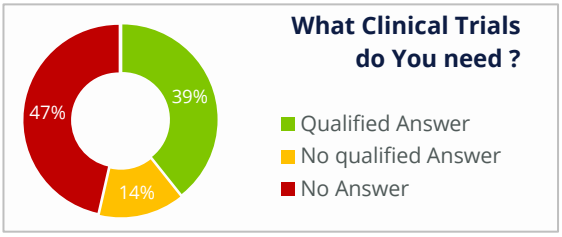
Most of the interviewees have the feeling that regulatory requirements regarding the clinical evaluations of medtech innovations will increase. Thus, medtech decision makers generally expect more studies in the future.

Nevertheless, more than a half of the interviewed startups assume that their own developments are not affected and that no own clinical trials need to be conducted.

What is the reason? Before or during founding, most of the startups have not yet laid out clear organizational responsibilities for clinical development. Martin Conrad of HiTec Consult comments: "While startups might underestimate the requirements, innovative developments at well-established SMEs are sometimes even cancelled because of the higher financial requirements."

Strategic Gap at Startups

Asked for the strategy and goals of potentially necessary clinical studies that might need to be performed, the answers of the startups revealed scanty knowledge and the strategic gap becomes evident: 61% of the interviewed startups could not define their need for clinical studies. Only 39% had a competent picture about the necessary clinical program.

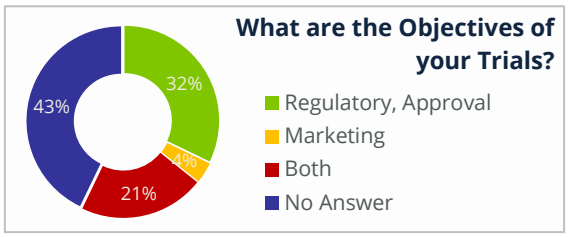


„Naturally, for young companies, financing issues and technical development hurdles attract the main focus of the management", Conrad continues.

However, for most of them who know their clinical strategy, the primary focus is to obtain the CE label for their product. Only a minority (25%) recognizes the strategic benefit of the clinical data for re-imbursement and marketing purposes.

Everybody suspects it. The interviewed startups expect that the amount of studies will almost double from 2014 to 2018.

Established mid-sized companies seem to be more mature on that. Based on the experience of past product approvals and market launches, they expect that the future study demand is mainly driven by re-imbursement and marketing purposes. Studies for pure CE labeling will be a minority. Accordingly, 67% of those companies have internal resources for study management.



Axel Fischer, CEO of Activoris Medizintechnik, adds: „the non-consideration of the clinical phase during the development of an innovation puts the business plan of a startup at risk. Some of the young companies answered that the clinical evaluation can just be arranged by literature, and by a close cooperation with the notified body. No question, this brings you one step ahead. But the goal of a development is to bring an innovation to the market, and, a CE label alone does not create any sales.

A clear Clinical Strategy is essential to Financing

This topic might also be interesting to the VC community. Dr. Christian Schneider, Managing Partner at Vesalius BioCapital Sàrl, comments: “We know the situation. If you are about to start a development today, you have to consider the competitive environment tomorrow.” At Vesalius, startup business plans should contain a clinical plan comparable to a phase 2 study with a three-digit patient number. “The size of the study is key for a credible marketing message – leading to a successful out-licensing of the project to a Global Player.”

In case no study is planned but becomes necessary for re-imbursement, fresh – and expensive – money has to be raised, while the patent clock counts down mercilessly.

Health Technology Assessments (HTA)

HTA reports, issued in Germany primarily by the Institute for Quality and Efficiency in Health Care (IQWiG), aim to assess effectiveness, safety and cost. HTA reports give an important input for the inclusion of innovative devices and procedures into the re-imbursement catalogue of the German social health insurance.

Theresa Hunger, former senior scientist at UMIT in Hall/Tirol (Austria) has worked on the development of guidelines for the assessment of medical devices and innovative procedures on a European level: “The trend of the payors’ re-imbursement strategy is characterized by assessments based on randomized prospective studies including patient-relevant endpoints. It is in the hands of the industry to deliver that evidence.” The expectations increase to demonstrate evidence by similar methods as known from pharmaceutical studies, particularly, for class IIb and class III devices.

The new § 137h of the German Social Security Code (SGB V) includes regulations for an early and systematic assessment of innovative high-risk devices in the stationary sector. Eventually, this means that clear evidence has to be presented if a manufacturer applies for re-imbursement.

The Bottom Line

Medical device clinical studies put new challenges in front of medtech companies with regards to business planning, clinical strategy, and financing of development projects.

Currently, it appears that this topic is somewhat underestimated by many companies and the know-how around clinical studies is only scarce. Especially startups struggle with planning a clinical study, and at the same time the value of ground-solid data for their marketing is not recognized. Recommendations:

More know-how around strategic clinical aspects is needed. This know-how should be added right at the beginning, to recognize any impact of the clinical plan to the product design. Starting thinking about a clinical plan only when it is about to hire a Clinical Research Institute (CRO) is too late. Endpoints need to be defined clearly and should be clinically *and* economically relevant.

Ideally, the clinical plan should be international. Startups need to give their developments into the hands of global players with the marketing power to launch products effectively. This exit will become more likely if a product has chances in different markets.

Early inclusion of the authorities. For example, BfArM in Germany offers consultancies during the development phase. So called "Scientific Advices" can be obtained for not more than 2,800 € for medical devices. Money well spent.

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