IRIS PRICING SOLUTIONS

Pricing a Digital MedTech Device for use in Clinical Trials

Focusing on **value** and how this can vary by trial design

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Client Background

About the Device

Our client, an established manufacturer of syringes, had developed a prototype digital injection device designed for use in clinical trials.

This **data-enabled injection device** would automatically capture injection data without interfering with the injection device usability. Specifically, the device would capture the start/stop time, completion and device ID. Using a cloud solution, this information would be available real-time to all relevant study stakeholders via the electronic Clinical Outcome Assessment (eCOA) platform used with the clinical trial.

The **target customers** would be either pharmaceutical companies or Contract Research Organizations (CROs), where the clinical trial design involved administration to subjects using subcutaneous injections.

The Challenge

The **project goal** was to help our client understand the business opportunity for this prototype device including:

- Does this device justify the investment needed to bring it to market?
- What is the market potential in major North American and European markets?
- How long would it likely take to gain customer acceptance?
- Who are the key decision-makers?
- Would market success just depend on stakeholders from the customer organizations, or would it also require broader approval, such as with regulatory authorities?
- Crucially, based on the device's value, what should the pricing structure be and at what price levels?

The Research Process

A Focus on Value

Our approach to this research project was to focus on value. This is about understanding what problems this technology could be used to solve, and how this might vary according to the characteristics of the clinical trial. It is also about understanding the financial value this technology could offer as justification for how it is priced.

In all, **30 qualitative interviews** were conducted amongst executives responsible for clinical trial decision making, and who had experience of running clinical trials using subcutaneous injections. Around 20 respondents were US-based, and the remainder were from Germany. Interviews were web-enabled to allow respondents to view stimulus material which described this technology, including use of a 2-minute video. There was no need for translation for the German interviews since, internationally, English is usually well understood by pharmaceutical executives.

This research study was conducted in mid-2021.

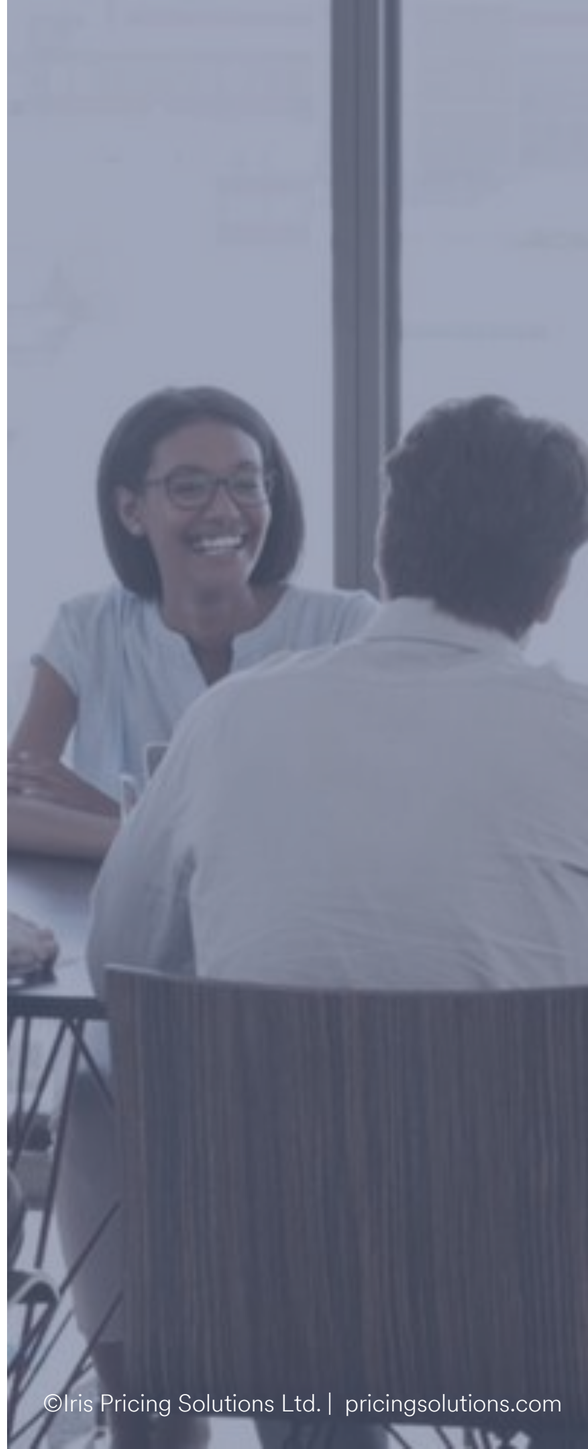
Clinical Trials in the Early 2020s

Clinical trials, which are used to establish the safety and efficacy of new medical products, are highly regulated. For clinical trials run in the US, the regulatory authority is the FDA. In Germany, depending on the type of product, regulatory oversight is provided by either the Federal Institute for Drugs and Medical Devices (BfArM) or the Paul-Ehrlich-Institute (PEI).

It is the responsibility of the pharmaceutical companies/CROs to demonstrate to the appropriate regulatory authority, or authorities, that the clinical trials that they run meet their high standards of safety, objectivity and reliability. Such rigour can be very expensive; Phase 3 clinical trials may cost as much as $50 million dollars to run.

Each clinical trial is designed specifically to the requirements of that trial. **The clinical trial team needs to consider** how to manage patient recruitment, trial efficiency, cost, patient compliance and keeping-up with an evolving technology and regulatory environment.

COVID-19 has made a major impact towards digitalizing aspects of the clinical trial process, especially in terms reducing the need for in-person contact. Indeed, trials for COVID-19 vaccines that were needed in response to the pandemic, demonstrated new ways of running rapid, large-scale clinical trials. There has been lobbying to maintain this shift with the creation of the #NoGoingBack movement, which was established “to preserve the bold new ways to conduct trials due to COVID-19.”



Impact

How our Client Benefited from Pricing Research

The shift towards digital technologies in clinical trials provided a **positive market environment** for customer consideration of the data-enabled injection device.

It was also clear that the injection device would need to be approved both by customers and by regulatory authorities. The device would also need to be fully tested before the ‘go live’ of any clinical trial. Once a trial has started, the clock would be ticking to get it completed as quickly as possible, with every effort made to minimize the risk of delays.

The results provided clear direction as to what the value drivers for adoption would be, along with financial value drivers, and how these could vary by clinical trial design. Pricing recommendations were guided by these insights in a way to best capture the value that the data-enabled injection device could deliver to customers.

Overall, our client was able to judge the business opportunity offered by their prototype injection device, as input to their own go/no go decisions on commercialization.

What's the Pricing Solutions Difference?

We are *always* thinking about value and pricing

We can apply universal pricing principles and best practices to the needs of a specific project. We are also subject matter experts in the MedTech space.

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