Leveraging Health Insurance Data for Accelerated and Targeted Recruitment in Clinical Trials in Germany

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Transforming trial recruitment in Germany:
A scalable model leveraging SHI data and direct patient engagement to drive efficient enrollment

Accelerating access to eligible patients:
Embedding SHI via integrated care contracts into the recruitment pathway to unlock untapped populations

Moving toward deployment:
First prototype currently active and underway

Challenge

Recruitment of suitable participants for randomized controlled trials (RCTs) remains a major bottleneck in clinical research, with significant operational and financial implications for industry. Conventional recruitment strategies account for approximately 32–40% of total study budgets, while even minimal delays can lead to substantial revenue losses and shortened effective patent protection periods. At the same time, increasingly stringent eligibility criteria and smaller, more defined target populations make patient identification more complex, contributing to high dropout rates of 30–40%.

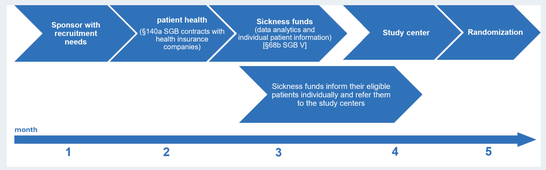
Despite these investments, awareness of clinical trial opportunities among patients remains limited, and key stakeholders—such as sickness funds—often lack transparency regarding available studies. This disconnect restricts access to potentially beneficial trials, particularly for patients with limited or no remaining therapeutic options. Addressing these structural inefficiencies requires scalable, data-driven approaches that improve visibility, streamline patient identification, and facilitate access to clinical research.

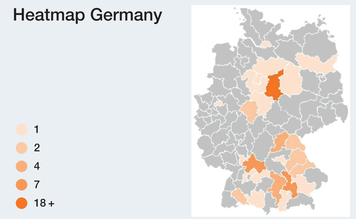
Solution Approach

We developed a novel, scalable recruitment model in collaboration with multiple German statutory health insurers (SHI), leveraging claims and diagnosis data covering more than 10 million insured individuals (>13% of the population). Within a legally compliant framework (§140a in conjunction with §68b SGB V), fully aligned with GDPR and German social law, eligible patients are proactively identified and contacted directly by their respective insurer.

This structured “push” approach enables precise patient identification based on real-world data, improves outreach efficiency, and increases patient engagement. In addition, ongoing communication and care coordination through the insurer support patient retention throughout the study pathway. Together, this model addresses key recruitment barriers by integrating data-driven targeting with trusted stakeholder engagement.

Proactive Targeted Patient Recruitment





Lessons Learned

- Regulatory tailwinds enable innovation: Recent developments in German legislation on digitalization and innovation create new opportunities for datadriven integrated care contracts.
- Improved recruitment efficiency for sponsors: The model enhances patient identification and enrollment in Germany, while enabling access to strategic advantages such as confidential pricing frameworks.
- Feasibility demonstrated: Initial prototype successfully launched in a rare cancer indication.
- Regulatory alignment is achievable: Integration of RCT requirements with the integrated care model is feasible, but requires dedicated support during initial implementation phases.

Stakeholder Perspective & Outlook

Evolving regulatory frameworks in Germany enable data-driven, integrated approaches to trial recruitment. Our model shows that collaboration with statutory health insurers can improve patient identification, accelerate enrollment, and enhance efficiency.

Stakeholder Perspective: Patients gain earlier access to innovative therapies and better care coordination. Sponsors and CROs benefit from faster, more costefficient recruitment and reduced dropout. Health insurers strengthen services and competitiveness, while policymakers support Germany’s position as an attractive clinical research location and improve system efficiency.

The successful launch of a first prototype in a rare cancer indication demonstrates feasibility. With appropriate implementation support, alignment between RCT requirements and integrated care models is achievable. Scaling this approach across indications offers strong potential to further improve trial performance and patient access.

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