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Clinical research in private hospitals: a perspective

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Abstract

Background The expansion of clinical research beyond academic hospitals into private hospitals is reshaping the way new therapies are tested and implemented. Traditionally, university and public hospitals have been the primary drivers of clinical research, yet private hospitals are increasingly positioned to contribute meaningfully to this landscape.

Discussion This perspective explores the opportunities and complexities of establishing a clinical trial unit within a private setting, highlighting strategies to conduct innovative studies and deliver high-quality, patient-centered research. While private hospitals may face initial challenges related to infrastructure, regulatory compliance, and quality assurance, they offer important advantages, including more rapid decision-making, streamlined administrative pathways, and efficiency in initiating and conducting studies, all while adhering to the same regulatory requirements.

Conclusion By positioning themselves as complementary partners to academic institutions, private hospitals can provide efficient and fast paced environments for industry-sponsored trials, ultimately enriching the broader research ecosystem. Most importantly, these developments enable the realization of personalized medicine, where cutting-edge, individualized therapies, particularly in oncology, can be directly tailored and delivered to patients, transforming the promise of precision medicine into real clinical outcomes.

Keywords Clinical research, Clinical trial unit, Private health sector, Private hospitals, Cancer vaccines

Background

Clinical research is the cornerstone of evidence-based medicine, enabling the systematic evaluation of novel therapeutics and ensuring that scientific discoveries translate into real-world benefits for patients. The rigorous methodology of clinical trials provides the foundation for regulatory approval, clinical guideline development, and ultimately, improved patient outcomes in routine clinical practice. Historically, academic centers such as university hospitals have served as the primary sites for clinical research, owing to their established infrastructure, concentration of expertise, and familiarity with regulatory and ethical frameworks. Yet, with the expanding pipeline of investigational products the capacity of

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academic centers alone is insufficient to meet the growing demand for timely, efficient, and diverse clinical trial activity [1]. Oncology remains the primary driver of clinical trial activity, with solid tumor therapies generating approximately USD 122 billion in global revenue in 2022 and representing one of the most active areas of global R&D investment [2]. This growing demand highlights the need to integrate private hospitals into the clinical trial ecosystem.

Private hospitals represent an important, though underutilized, complement to traditional research sites. Their broad distribution, accessibility to heterogeneous patient populations, and potential for faster recruitment make them well positioned to address critical bottlenecks in the current research ecosystem. Participation in clinical trials can confer significant advantages for private practices, including early access to innovative therapies for patients, enhanced institutional reputation, and diversification of revenue streams. Compared with academic centers, private hospitals may also offer greater flexibility in organizing trial activities. Smaller and more focused organizational structures can facilitate more agile decision-making, without competing priorities, or large bureaucratic processes. However, successful involvement of private practices ultimately depends on sustained interest and investment in healthcare innovation and research infrastructure.

In this perspective, we examine the practical considerations for establishing clinical trials in private healthcare settings. Specifically, it explores the infrastructure required for successful implementation, the operational and regulatory challenges involved, and the potential advantages for both patients and providers. Particular attention is given to the context of personalized medicine, where the rapid evolution of highly targeted and complex therapeutic approaches demands more agile research models. Expanding trial activity into private clinical practice may therefore represent not only a strategic opportunity but also an essential step to ensure that advances in translational research are delivered efficiently and equitably to patients. Our discussion draws on direct experience in developing clinical research infrastructure within private hospitals, complemented by available published and publicly accessible data, with the goal of offering practical guidance for institutions seeking to implement similar initiatives.

Core components of clinical research infrastructure

Establishing a robust infrastructure is essential for institutions aiming to participate in clinical research. While many practices already have elements that can be adapted for research purposes, private hospitals may often need to create ad hoc tools and infrastructure that are not traditionally present in a private environment in comparison to academic centers, or to substantially change and adapt already existing frameworks and procedures for clinical trial purposes. Overall, successful trial implementation requires careful consideration of three interdependent components: regulatory and quality frameworks, human resources and training, and adequate facilities and equipment. Together, these form the backbone of a sustainable and compliant research environment (Fig. 1).

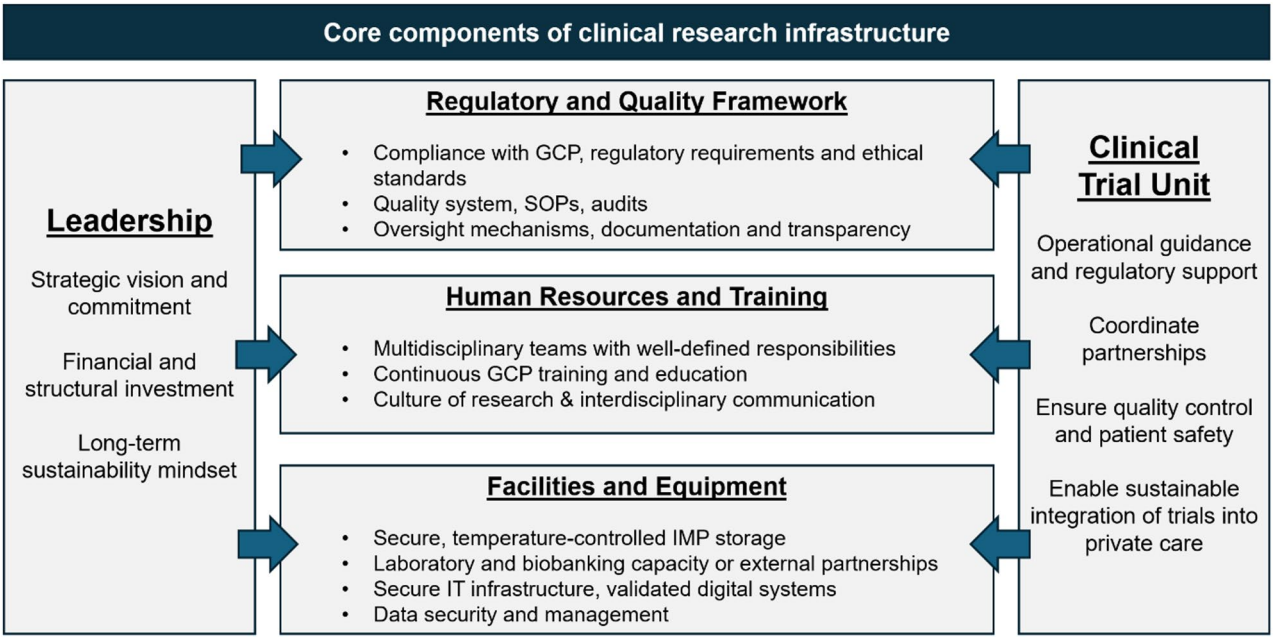

Fig. 1 Core components of clinical research infrastructure. Establishing a successful clinical trial program and fostering a strong research culture depend on close collaboration among leadership, medical personnel, and the administrative and scientific support teams within the Clinical Trial Unit

Regulatory and quality framework

Compliance with regulatory standards is the foundation of any clinical trial program, ensuring not only the validity of study outcomes but also the protection of patient safety and rights. This means aligning research operations with internationally recognized regulatory, ethical and scientific principles such as Good Clinical Practice (GCP) [3] and adhering to the requirements of regulatory authorities, including Swissmedic (Switzerland), the U.S. Food and Drug Administration (FDA), and the European Medicines Agency (EMA). This regulatory environment can be complex, particularly for non-academic institutions such as private hospitals where prior experience with clinical trials may be limited. However, meeting these standards is indispensable for credibility and for the acceptance of study data by sponsors and oversight bodies.

A key element in achieving compliance is the development of a comprehensive quality management system (QMS). This system should be supported by well-defined standard operating procedures (SOPs) that provide clear guidance on each stage of trial conduct, from patient recruitment and informed consent to data entry and reporting of adverse events. In many cases, institutions can build upon their existing clinical QMS to create a tailored framework for research activities. Designating a dedicated quality officer or leveraging an existing role can ensure continuity, accountability, and alignment between clinical care and research operations.

Oversight mechanisms represent another critical dimension of regulatory compliance. Institutions undertaking clinical research activities must not only understand the processes of Ethics Committees but also be prepared for monitoring visits, audits and inspections visits conducted by sponsors or regulatory authorities. In practice, this requires ongoing, meticulous documentation beyond the initial regulatory and ethical submission, including continuous recording of informed consent, tracking protocol deviations, maintaining accountability for investigational medicinal products (IMPs), reporting adverse events, and ensuring complete, accurate medical records. Amendments to the protocol or study documents must also be documented and communicated promptly to all relevant parties [4]. These processes demand meticulous documentation, transparency in operations, and the ability to demonstrate adherence to trial protocols and GCP standards at all times to ensure the rights, safety, and well-being of trial participants, while generating reliable, credible clinical data. Such readiness is often a significant cultural shift for private practices accustomed primarily to routine patient care, where documentation practices may vary between physicians. Regular training and cross-disciplinary communication are therefore central to establishing a sustainable system.

The dynamic and rapidly evolving nature of the regulatory landscape introduces additional layers of complexity. Submitting a clinical trial application to regulatory authorities is rarely a straightforward process in real life, as requirements differ significantly across jurisdictions. Country-specific, in-depth knowledge of regulatory requirements is therefore essential. In the European Union (EU), clinical trials are governed by the legal framework set out in EudraLex, particularly Volume 10 for clinical trials [5]. In recent years, new EU healthcare regulations have been introduced that aim to standardize implementation across member states while maintaining high ethical and scientific standards. However, the simultaneous application of multiple overlapping regulations, including the Clinical Trials Regulation (CTR), Medical Device Regulation (MDR), and In Vitro Diagnostic Regulation (IVDR), creates compliance complexities for sponsors, increasing administrative and financial burdens despite the potential benefits of advancing patient-centered clinical research [6].

In the European Union, clinical trials require a Clinical Trial Application (CTA) submitted under the framework of the CTR, with approval granted by national competent authorities alongside ethics committees [7]. Among the most significant challenges are ethical and regulatory barriers, with a major issue being the lack of harmonization both within the EU and between the EU and other developed countries [8]. Beyond the EU, regulatory frameworks vary across countries, and one must also navigate differing legal and procedural requirements in non-EU regions. In Switzerland, authorization follows a similar dual pathway under the Federal Act on Research involving Human Beings (Human Research Act, HRA) and the Clinical Trials Ordinance (ClinO), where both Swissmedic and local ethics committees must approve before a study can begin [9, 10]. In the United States, clinical research is regulated by the FDA under Title 21 of the Code of Federal Regulations (CFR), with an Investigational New Drug (IND) application required when a study involves the use of an unapproved drug or an approved drug in a new indication, dose, or formulation [11, 12]. While differing in procedure, these systems share the common objective of safeguarding participants and ensuring that clinical trials are scientifically and ethically sound.

In addition, while the International Council for Harmonisation (ICH)-GCP guidelines [3] provide an international framework that harmonizes these different systems, they serve as guidance and as the ICH guidelines are regularly updated, researchers must remain up to date while also ensuring full compliance with local legal requirements. To help navigate in this complex

landscape, several regulatory authorities such as Swissmedic [13] and the FDA [14], organizations such as the Swiss Association of Research Ethics Committees [15] or initiatives such as the Accelerating Clinical Trials in the European Union (ACT EU) initiative [16] have implemented multiple sets of guidelines which are intended to provide clarity but, in practice, often add to the volume of information that must be mastered. In addition, the technical wording of regulations and guidelines can be difficult to interpret, especially without prior regulatory and legal experience. Thus, regulatory intelligence and continuous interaction with health authorities are required to identify and anticipate potential hurdles.

Furthermore, the advent of personalized medicine, driven by pharmacogenomics and the integration of genomic, clinical, and hereditary data, offers highly tailored healthcare solutions but introduces significant regulatory complexity. Existing frameworks are often challenged, as regulatory agencies must continuously adapt policies to evaluate the safety, effectiveness, and the ethical considerations of increasingly individualized therapies. Reliance on sensitive genetic and biometric data raises critical data privacy and security concerns, requiring robust governance, encryption, and consent mechanisms to protect patient information. The increasing focus on using molecular information to tailor therapies has driven a substantial rise in precision medicine approvals by the FDA, with personalized medicines consistently representing over one-third of all drug approvals in 2023, including molecular, gene-, and cell-based therapies [17]. This trend highlights the ongoing commitment to supporting treatments that leverage biomarkers to guide individualized patient care. As the field evolves rapidly, effective implementation while maintaining compliance and fostering innovation demands adaptive, forward-looking regulatory strategies, together with concurrent advancements in ethical and legal frameworks.

In this context, the establishment of a dedicated, multidisciplinary support team within a clinical trial unit (CTU) is essential; such a team can provide guidance across regulatory, scientific, and operational domains, facilitating smooth trial initiation and ensuring efficient, compliant conduct throughout the study. The core function of a CTU is to provide the specialized infrastructure needed to navigate the complex and highly varied regulatory landscape. The statement that compliance is a major challenge is an understatement, as the requirements differ dramatically depending on the type of the trial. A dedicated research unit, with its regulatory affairs specialist, provides the essential engine to meet these extensive demands, transforming a physician's scientific question into a compliant, executable clinical trial. Moreover, engagement with regulatory authorities through scientific advisory meetings can provide valuable guidance during the planning and implementation phases, helping private hospitals anticipate challenges and align their practices with evolving expectations. Such proactive dialogue also enhances credibility and demonstrates not only a commitment to maintaining the highest research standards but also awareness of the regulatory system's complexity and commitment to navigating it effectively.

Human resources and training

Human resources represent the cornerstone of any successful clinical research program. Unlike academic medical centers, which often have dedicated research departments, private hospitals must deliberately invest in building a team with the necessary expertise to support trial activities. At the core of this team are research coordinators, study nurses and pharmacists, who play a critical role in bridging the gap between investigators, patients, and sponsors. They provide regulatory, technical, administrative, and operational support, ranging from patient recruitment and scheduling of study visits to data collection, protocol adherence, and reporting of adverse events. Their work ensures that investigators are able to focus on clinical decision-making while the operational aspects of the trial are managed effectively by dedicated and specially trained staff. While day-to-day study activities may be delegated to study staff or external parties, the ultimate responsibility for the proper and ethical conduct of the study remains with the principal investigator. Beyond regulatory obligations, investigators are responsible for producing high-quality, meaningful scientific research while maintaining public trust; acting with integrity, ensuring proper training, and providing oversight are essential to achieving reliable data and credible outcomes [18].

Continuous training is a fundamental requirement for all staff involved in clinical research. Compliance with GCP is not optional, but an internationally mandated standard that underpins the ethical and scientific validity of every study. Initial training provides staff with foundational knowledge for trial participation, while ongoing education ensures they stay current with evolving regulations, technologies, and best practices. Given the frequent turnover of personnel and the reliance on part-time roles across both academic and private settings, sustained investment in training safeguards against the erosion of institutional knowledge. In addition, the interdisciplinary nature of clinical research demands clear communication channels among physicians, nurses, coordinators, pharmacists, and administrative staff. Establishing a culture of research within the clinic, where trial activities are integrated into, rather than seen as separate from, routine clinical care, fosters efficiency and reduces the likelihood of errors or protocol deviations. Ultimately, well-trained and adequately supported personnel are the key drivers

of both compliance and quality in both public and private-sector clinical research.

Facilities and equipment

Beyond personnel and regulatory frameworks, the physical and technical infrastructure of the institution must be adapted to meet the stringent requirements of clinical research. A critical consideration is the secure storage of investigational products. This includes access to temperature-controlled units and cold-chain logistics to ensure the integrity of drugs and biologics throughout the duration of a study. Detailed documentation of storage conditions and controlled access systems are essential to maintaining compliance and safeguarding both patient safety and data validity.

Laboratory capacity represents another essential component of clinical research readiness. Academic hospitals and research centers typically benefit from direct collaborations with, or immediate access to, well-equipped laboratory facilities. In comparison, while some private hospitals may already have basic laboratory facilities on-site, others should consider establishing a dedicated space for at least simple storage and sample processing if they aim to participate in trials with exploratory research questions. Translational analyses usually involve the collection of biological specimens (e.g. blood, urine) that are then analyzed to track the presence of the drug of interest, specific metabolites, blood composition, or other relevant analytes, often over time. For more complex analyses such as for example tissue multiplex staining and analysis, or cell markers characterization by flow cytometry, collaborations with accredited external laboratories may still be necessary for private hospitals.

Beyond routine sample handling, robust biobanking capabilities are a key consideration for translational research. Big academic centers often maintain high-quality biobanks with established governance structures, a general informed consent and a comprehensive QMS, enabling standardized collection, storage, and annotation of human biospecimens such as blood, tissue, and other fluids [1, 3]. For smaller hospitals, creating a full-scale biobank can be resource-intensive and may not always be feasible or financially sustainable [19]; however, study-specific, temporary storage solutions or collaboration with academic or commercial biobanks are possible without the requirements of permanent infrastructure [20]. Nevertheless, biobanks are essential components of research infrastructure, especially in the context of personalized medicine, but raise complex ethical, legal, and social challenges, including donor privacy, informed consent, and the management of intellectual property arising from discoveries using biospecimens, which are addressed through national laws, international standards, and biobank-specific governance policies to ensure quality, integrity, and responsible access to samples and data for research [21].

Equally important is the implementation of secure information technology systems to protect personal and clinical data. These systems must ensure data integrity, traceability, and compliance with regulatory requirements. Electronic case report forms (eCRFs) and validated digital platforms play a central role in modern clinical trials, enabling accurate data entry, monitoring, and reporting. Academic centers often benefit from institutional access to well-established data capture systems such as REDCap or SecuTrial, which are secure, web-based platforms widely used in non-profit research environments. Such platforms already support compliance with major data protection and research standards, including General Data Protection Regulation (GDPR), 21 CFR Part 11 (FDA) and the Health Insurance Portability and Accountability Act (HIPAA), and benefits from a large international consortium offering shared expertise and support. In contrast, private hospitals must identify and contract suitable commercial vendors that meet the same regulatory and security standards. Selecting an appropriate eCRF platform requires careful evaluation of vendor compliance, data hosting infrastructure, and suitability for study-specific requirements. To ensure compliance and quality, private institutions can collaborate with specialized consultants or partner with dedicated Contract Research Organizations (CROs) for vendor oversight and data management, including CRF design and development, electronic database setup, clinical coding, reconciliation of external and safety data, among others. Such partnerships allow private hospitals to achieve regulatory-grade data integrity and operational efficiency comparable to academic research centers. Ultimately, investing in robust IT infrastructure, cybersecurity measures and professional data management oversight is essential to guarantee data quality, ensure patient confidentiality, and support the credibility of research outcomes generated within private healthcare environments.

Together, these facility and equipment considerations form the practical backbone of trial operations. For private clinics in particular, strategic investment in these resources, either independently or through partnerships, represents a necessary step toward building a sustainable and credible research program. Once these foundations are established, clinics can begin to integrate research activities into routine care delivery. Implementation in private practice offers several advantages for both patients and providers, but it also introduces unique challenges that must be anticipated and managed. The following sections will examine these opportunities and challenges in greater detail.

The sponsor

In clinical research, the Sponsor is the organization or institution responsible for initiating, managing, and financing, and ensuring appropriate insurance coverage for a clinical trial. This may include pharmaceutical companies, academic institutions, government agencies, or private organizations. A dedicated research unit can provide the expertise to manage these distinct pathways, distinguishing between industry-sponsored trials and investigator-initiated trials (IITs).

The Sponsor assumes overall legal responsibility for the study, ensuring that it is conducted according to the protocol, regulatory requirements, and quality assurance systems, even if operational activities are delegated to other parties. In many cases, for industry-sponsored trials, the Sponsor is a pharmaceutical company that developed the investigational product and funds the trial, while hospitals or clinics are engaged as investigator sites under contractual agreements. In this model, the external Sponsor remains responsible for interactions with regulatory authorities, including clinical protocol development, dossier submissions, securing approvals from national competent authorities, and overseeing trial conduct and safety reporting.

Sponsors in clinical trials face significant challenges including navigating complex and varying regulatory requirements across regions, managing legal and financial liabilities such as insurance and participant compensation, and handling the administrative, logistical, and ethical responsibilities of trial design, investigational product management, and data integrity. They must also address conflicts of interest, ensure publication transparency, and maintain oversight when trials involve multiple sites or international partners [18, 22]. These combined demands make the Sponsor's role highly accountable and operationally intensive. In this context, the research unit functions as a highly competent and reliable partner. Its role is to ensure meticulous adherence to the protocol and GCP standards at the site level and maintain pristine documentation for sponsor audits and regulatory inspections. A clinic with a robust research unit, complete with established SOPs and a QMS system, becomes a preferred site for sponsors, as it significantly de-risks the trial from their perspective.

Increasingly, however, hospitals and clinics act as both the investigational site and the Sponsor, a model particularly common in the public sector where therapies originating in academic or hospital laboratories are advanced into clinical trials led by the same institution, the so-called "bench-to-bedside" process. More recently, private hospitals have also begun adopting this approach, combining clinical operations with the Sponsor role (see Sect. 5 for a descriptive institutional case study). In such IITs, the regulatory burden shifts dramatically and becomes far more substantial. The physician and their institution assume dual Sponsor-Investigator responsibilities, meaning they are directly accountable for the entire regulatory lifecycle, a task that is virtually impossible without the infrastructure of a formal research unit with extensive prior experience in clinical research, regulatory compliance, and operational management.

When a private clinic acts as the Sponsor, it must not only maintain the above-mentioned regulatory and operational structures but also implement a Clinical Development Division within the Clinical Trial Unit to oversee drug manufacturing. Manufacturing must comply with Good Manufacturing Practice (GMP) regulations [23], which ensure products are produced under controlled conditions that safeguard patient safety, product quality, and expected efficacy. As most hospitals lack in-house GMP facilities, these activities are frequently outsourced; nonetheless, the hospital remains ultimately responsible for GMP compliance and manufacturing design. This requires specialized staff with expertise spanning translational research, pre-clinical science, and regulatory standards.

Advantages of conducting research in private clinics

Private hospitals offer organizational advantages that can significantly accelerate the implementation of clinical research. Leadership in these settings can directly drive innovation, prioritizing research initiatives without the procedural constraints often encountered in large academic institutions. Moreover, while research activity is rightly embedded as a core responsibility of medical doctors in academic institutions, this framework may also foster intra-institutional competition for projects, further slowing initiation and complicating collaboration. On the other hand, the non-academic structure affords physicians greater autonomy to pursue research initiatives without the obligation to supervise large numbers of assistant medical doctors, thereby avoiding additional workload and ensuring that clinical research activities remain focused and efficient.

Operational flexibility of private clinics, coupled with rapid decision-making, allows strategic initiatives to be implemented more swiftly than in bureaucratically structured organizations. Processes such as contract negotiation and revision, which can be protracted in university hospitals due to layered approvals and formal "invitation to tender" procedures, are often managed more efficiently in private settings. One of the key advantages of conducting clinical research in private is operational flexibility, particularly in the speed of trial activation. The median activation time for Phase I–III trials has been reported at over eight months in academic medical centers and hospitals, compared with just over four

months in independent sites or physician practices [24, 25]. In our own experience, although preliminary, within the Swiss Medical Network, trial initiation, including contract and budget negotiations as wells as operational readiness, can occur within just 6 to 8 weeks for studies that are already activated in Switzerland and approved by Swissmedic, or for late-phase (e.g., Phase III) trials. This highlights the potential advantages of agile organizational structures, where streamlined administrative processes and close coordination across teams can expedite study start-up. However, such efficiency is context-specific and may vary depending on institutional resources, staffing, and workload. Nevertheless, this operational efficiency is particularly valued by pharmaceutical sponsors, who often operate under competitive timelines and welcome collaborations with centers capable of ensuring rapid startup, agile communication, and reliable execution.

Evidence from the U.S. highlights the delays inherent in traditional academic-centric models, especially in fields such as oncology with more and more complex study protocols [26]. The administrative process associated with trial activation includes up to 30 different activities, involves up to 11 participants, and lasts on average, from 44 to 172 days and thus is associated with considerable costs. In a study by Martinez et al. 147 clinical trials were evaluated at the University of South Florida. The median time to activate an industry-sponsored trial was 69 days and contract and budget negotiations represented the most complex and time-intensive parts of the administrative process, with average durations of 54.9 and 46.3 days, respectively [27]. A 2018 survey of 61 cancer centers reported a median trial activation time of 167 days, with budget and contract negotiations, multiple trial amendments, staff turnover, and lack of responsiveness being major contributors to delays [28]. The problem of prolonged trial activation is not limited to the U.S. as EU-funded and other international clinical trials face similar administrative and regulatory constraints, which can substantially delay study initiation [29, 30]. Together, these metrics provide concrete evidence of the structural friction within large academic systems, highlighting a critical need for more agile and efficient research partners to accelerate the pace of therapeutic development. However, it is important to note that information on trial initiation times, operational efficiency, and patient recruitment is often not publicly available, neither from academic institutions nor industry. Such transparency would help promote more efficient, patient-centered trial operations and encourage broader dissemination of knowledge in the field.

In addition to slow initiation times, another persistent bottleneck in clinical research is poor patient accrual, especially in oncology, where a large proportion of trials fail to meet minimum recruitment targets [31] This challenge is common to both public and private institutions and has been amplified by increasingly narrow eligibility criteria and complex study protocols [32]. A promising way forward lies in leveraging networks of sites and strengthening collaboration across institutions to broaden access to eligible patients. In this respect, private practices hold a distinct advantage: physicians often know their patients personally and maintain long-standing relationships, allowing them to more effectively identify individuals who could benefit from trial participation. This closer connection also fosters greater patient trust in the system, which is critical for overcoming skepticism and ensuring that patients feel comfortable enrolling in clinical research. A qualitative interview study among industry and contract research organization (CRO) representatives in the Nordic countries found that successful patient recruitment is heavily dependent on sites having a clear understanding of, and access to, their own patient population. Interviewees described how sites that leverage their electronic health records to identify eligible patients typically recruit more effectively. In contrast, poor recruitment was most often traced back to insufficient feasibility evaluations that overestimated a site's patient pool [33]. These findings mirror broader European experiences: a qualitative study across Switzerland, Germany, and Canada identified overoptimistic recruitment projections, narrow eligibility criteria, and a lack of structured feasibility planning among the main drivers of trial discontinuation [34]. The implication is clear: clinicians who know their patients intimately, typically found in private hospitals with stronger patient relationships, are better positioned to assess trial suitability and recruit effectively while minimizing burden for trial participants. While this proximity between physicians and patients can raise ethical considerations, particularly regarding autonomy and the need to avoid undue influence. Nevertheless, the same ethical and regulatory standards apply across all institutions, both public and private: patients must be given sufficient time for consideration before signing informed consent, in accordance with GCP. Ensuring robust consent processes and transparent patient education therefore remains essential to uphold voluntary participation and maintain trust.

The primary strategic advantage of private hospitals in patient recruitment and retention lies in their ability to combine trusted physician-patient relationships with a hospitality-driven care model. This trusted endorsement, paired with high-touch support from dedicated research nurses or patient navigators, fosters confidence, reduces anxiety, and enhances retention throughout the study journey. Private institutions also benefit from a long-standing tradition of offering hotel-like services and multilingual support, making participation especially appealing for international patients seeking high-quality,

individualized care. For example, programs such as Genolier Patient Services, with more than 25 years of experience in supporting foreign patients, demonstrate how private hospitals can attract a diverse and global patient population by offering tailored, culturally sensitive services [35]. This capacity not only broadens the recruitment pool but also ensures more representative participation in clinical research. By blending operational excellence with patient-centered hospitality, private hospitals transform clinical trials into a seamless extension of care rather than a disruptive experience, thereby driving both higher enrollment and stronger long-term retention.

Participation in clinical trials can confer significant advantages for private practices, including enhanced institutional reputation and diversification of revenue streams. Investing in clinical research within private hospitals generates a dual return on investment: beyond the direct financial gains from industry-sponsored studies, such programs create strategic value by signaling innovation and positioning the clinic as a center of excellence. This dual benefit strengthens both market differentiation and long-term competitiveness in the healthcare environment. Importantly, the advantages extend across multiple dimensions: supporting market differentiation, fostering patient retention, and generating a reputational halo that attracts physicians, sponsors, and new patients.

Patients increasingly view access to innovative therapies as a marker of quality, and when those options are offered locally rather than only at academic centers, patient retention improves. By conducting clinical research, private hospitals can generate revenue from study activities while also benefiting from downstream gains such as higher clinical volume and improved patient experience, both of which are positively associated with greater long-term revenue in private hospitals and in general higher proportion of elective patients and lower costs as shown in a study conducted in 82 publicly and 50 privately owned Swiss acute-care hospitals [36]. In this context, the establishment of a dedicated and multidisciplinary support team within a CTU constitutes a cornerstone of institutional capacity, but it represents a significant financial undertaking that demands meticulous planning and a clear understanding of its complex cost structure. While revenue is generated through per-patient fees and other sponsor payments, achieving profitability hinges on rigorous feasibility analysis and skilled budget negotiation. This framework underscores that a research program is not a simple ancillary service but a complex business unit requiring substantial upfront capital and operational expertise. What is particularly noteworthy is that clinics engaged in research not only generate valuable additional revenue streams from industry-sponsored trials but also strengthen, at the same time, patient loyalty and long-term retention.

In private practice, in contrast to larger academic institutions, small teams of highly qualified individuals can rapidly bring together scientific, regulatory, and operational expertise. When composed of individuals with substantial academic experience, these teams bring a comprehensive understanding of the entire research continuum, from protocol design and regulatory approval to operational readiness and patient engagement. This contrasts with many industry-based models, where responsibilities are often fragmented across departments, resulting in a less holistic view of the clinical trial process. In private hospitals, engaged leadership can further enhance this efficiency by fostering an "academization" of private clinical practice, encouraging physicians and researchers with academic backgrounds to maintain a dual role that combines rigorous scientific inquiry with the agility of private healthcare. Leveraging this dual perspective enables private institutions to bridge the gap between the academic and private sectors, promoting innovation while preserving methodological and ethical standards characteristic of academic research.

With the support of engaged leadership or investors, these teams operate with streamlined communication and reduced administrative overhead. The financial advantages of maintaining a smaller workforce, both in research and in clinical teams, allow resources to be allocated more strategically. Importantly, to compensate for the limited in-house infrastructure typical of smaller organizations, private hospitals can strategically contract consultants and outsource specific activities, gaining access to specialized expertise while preserving operational flexibility. In Switzerland, this model is reinforced by the favorable environment of the "Health Valley," where a dense network of biotechnology, pharmaceutical, and service providers around the Lake Geneva region enables clinics to find expertise locally and establish productive industry collaborations. These partnerships not only expand the scope of trials that private hospitals can undertake but also position them as valuable contributors to innovation in translational medicine, facilitating access to novel investigational products, early-phase studies, and exploratory research opportunities.

Over time, the presence of a robust research program generates a reputational halo effect: the clinic is seen not only as a place for care, but as a forward-looking institution contributing to medical progress. We believe, this prestige strengthens trust among patients within the doctor-patient relationship, raises the profile of the clinic in the eyes of investors, and attracts high-caliber physicians and institutions that want to be associated with an environment of innovation. From a European perspective, National Health Service (NHS) England's guidance

underscores that good research financial management, including specialized costing, income distribution, and transparent accounting, is essential for maximizing the value of research to both institutions and patients, highlighting that robust financial systems underpin effective and sustainable research delivery [37]. By integrating meticulous financial management with a clear strategic vision, an initial investment in a CTU or similar infrastructure can evolve into not only a diversified revenue stream but also a strategic engine that enhances the clinic's financial health, clinical capabilities, and competitive position over the long term.

Taken together, these advantages highlight the agility and strategic potential of private hospitals in advancing clinical research making them a compelling complement to academic centers, yet they must be weighed against a distinct set of challenges that accompany research outside of traditional academic settings.

Challenges in private clinic research

While private hospitals offer significant advantages for clinical research, they also face distinct challenges, particularly during the early stages of implementation. Many practices lack dedicated research infrastructure, such as laboratories for sample processing or secure storage for investigational products, and may not have access to certain clinical specialties, like intensive care, which can limit the scope of trials that can be undertaken. Very early-phase, first-in-human or high-risk interventional studies, for example, may be unsuitable in settings without the capacity to manage acute complications. Nevertheless, private hospitals remain fully capable of conducting a wide range of clinical trials to the same standards as academic centers. Their participation does not aim to duplicate efforts but to complement the national research landscape, alleviating oversaturation of academic sites and expanding patient access to innovative therapies for example in highly specialized areas such as theranostics in nuclear medicine.

Establishing even a modest research platform, including data management systems, trained personnel, and basic laboratory capabilities, requires upfront investment and careful planning. Moreover, budgeting clinical trials is notoriously complex, and even academic institutions often grapple with underestimating costs due to overoptimistic feasibility projections and heterogeneous budgeting tools as shown in a meta-research study in Switzerland [38]. In contrast, private hospitals typically have more experience operating under business models, which can help them navigate these financial complexities more effectively. By approaching research development as a staged process, within a business plan, clinics can start small, progressively build capacity, and align resources with trial opportunities, thereby mitigating financial risk while creating a sustainable foundation for clinical research.

Navigating compliance requirements without institutional support can be burdensome for private hospitals and physicians who may feel reluctant to undertake this responsibility [39]. Ethics submissions, regulatory approvals, and adherence to GCP all demand time, expertise, and careful attention to detail. For this reason, setting up a dedicated CTU is a necessity, as it can provide guidance, streamline processes, and ensure that all regulatory and administrative obligations are met efficiently. Once established, such a unit creates a reliable framework that enables compliant and well-organized trial conduct, reducing the learning curve for the clinic and its staff. Systematic evaluations of CTUs in Swiss academic hospitals have shown similarly positive impacts on research quality, efficiency, and compliance [40]. Taken together, the benefits of CTUs should not be limited to large academic institutions, private hospitals and other healthcare settings can also leverage such structures to streamline research operations, support staff, and enhance study outcomes.

Additionally, in private practice, clinical research is often not a formal component of physicians' professional responsibilities, making it challenging to balance trial activities with routine patient care. Beyond the regulatory and procedural requirements, integrating research into private hospitals necessitates a broader operational transformation. Staff at all levels, including physicians, nurses, coordinators, and administrative personnel, must adapt to workflows that combine routine patient care with research responsibilities, often requiring reallocation of time and resources. Building a culture of research involves fostering shared ownership of trial objectives, continuous education on regulatory and scientific standards, and regular cross-disciplinary communication to maintain engagement and accountability. Leadership support, transparent incentives, and recognition of research contributions are critical to sustain motivation and embed research practices into daily operations.

Equally important is maintaining effective communication across all levels of the organization. At the governance level, clear and regular reporting on research progress helps keep leadership engaged and ensures strategic alignment. On the ground, close day-to-day coordination between investigators, research nurses, and study coordinators is vital to ensure smooth operational conduct and a positive patient experience. These communication pathways are often more direct in smaller private hospitals, where team members work in close proximity and know each other well, enabling a more agile and cohesive response to trial demands. Such proximity fosters trust, accountability, and a shared sense of purpose,

key ingredients for a sustainable, high-quality research environment in private healthcare settings.

Ensuring strong physician engagement is therefore essential to integrate research effectively and elevate the clinic's capacity for high-quality clinical studies. When structured appropriately, clinical trials allow physicians to contribute to meaningful scientific advancement, provide patients with access to innovative and potentially life-changing investigational therapies, and enable clinics to expand their patient population and clinical offerings, attracting individuals seeking advanced care options. Over time, as research workflows become integrated and supported by clear incentives, clinicians can participate in trials without undue burden. Similarly, quality assurance and data management, which may seem daunting at first, can be effectively supported through the implementation of a robust quality system, guided by a dedicated CTU, to help ensure consistent, reliable, and compliant trial conduct. Beyond the basic transition from paper-based to digital records, private hospitals must also address the broader information-technology (IT) infrastructure challenges that accompany modern clinical research. This includes developing, upgrading, or implementing secure and interoperable Electronic Health Record (EHR) systems where none currently exist, ensuring data standardization, and enabling compliant data exchange across multiple sites. However, the digitalization of health data remains a complex undertaking, as demonstrated by ongoing efforts to implement electronic patient records (EPR) across Europe. The forthcoming European Health Data Space (EHDS) [41] aims to create a harmonized framework for the exchange and secondary use of health data, yet significant barriers persist, including fragmented systems, limited interoperability, and uneven regulatory readiness across regions. A 2022 WHO Regional Office for Europe survey revealed that while most Member States have adopted national strategies for EHR implementation, major challenges, such as insufficient funding, technical capacity, and lack of standardized interoperability protocols, continue to impede progress [42]. These findings illustrate that building a truly interoperable digital health ecosystem requires not only advanced IT infrastructure but also sustained investment, governance, and cross-sector coordination. For research centers, such hurdles are particularly relevant when participating in multi-site or international collaborations, where secure and standardized data exchange is critical to ensure quality and compliance.

Overall, the challenges faced by private hospitals are largely front-loaded, reflecting the initial investment and learning curve required to establish robust systems. Once these foundations are in place, clinics can contribute meaningfully to clinical research in a sustainable and highly efficient manner, setting the stage for practical examples, such as the implementation of personalized therapies, which illustrate the real-world feasibility of conducting complex research in a private setting.

A descriptive institutional case study of personalized therapies in a private hospital

Clinical research within private hospitals and clinics is not a novel concept per se but rather an evolving and expanding dimension of modern healthcare. Across Europe and beyond, several private institutions have already demonstrated how private-sector medicine can contribute meaningfully to scientific discovery, translational research, and innovation in patient care. For example, the Vall d'Hebron Institute of Oncology (VHIO, Spain) has operated a dedicated Clinical Trials Office since 1997, coordinating hundreds of phase I–IV oncology and hematology trials annually through multidisciplinary teams of coordinators, data managers, and regulatory experts. Similarly, the Hirslanden Group in Switzerland has established a CTU, supporting investigator-initiated and multicentre studies in highly specialised medicine and health services research. Similar initiatives can be found across Europe and the United States, such as the Groupe Hospitalier Privé Ambroise Paré–Hartmann (France) and the HCA Healthcare Research Institute (United States), where private hospital groups have developed research and innovation departments or clinical trial networks to provide patients access to novel therapies and to integrate research into routine care pathways. These examples illustrate that private hospitals can successfully integrate clinical research structures that align with translational and precision medicine goals. Building such initiatives, although ambitious, is demonstrably feasible when leveraging prior experience, established frameworks, and institutional "savoir-faire." The following section outlines our own experience and practical approach to developing sustainable, high-quality clinical research infrastructure within private hospitals at the Swiss Medical Network.

The Swiss Medical Network is one of the largest private healthcare providers in Switzerland, comprising a network of clinics, hospitals and medical and competence centers committed to delivering high-quality patient care while fostering innovation and clinical research. Within this network, the Clinique de Genolier is strategically located adjacent to the Genolier Innovation Hub, an environment that encourages collaboration with academic institutions, biotech companies, and translational research initiatives. This positioning provides a unique opportunity to integrate cutting-edge scientific discoveries into clinical practice within a private hospital setting.

The clinic has long participated in clinical research, primarily through Phase III and observational studies conducted within the framework of breast center

certification and academic collaborations with the Swiss Cancer Institute (SCI, formerly SAKK). The establishment of a dedicated CTU has since expanded these activities, embedding research within the existing QMS and providing a structured framework for regulatory oversight, operational consistency, and partnership development. This progressive implementation, as illustrated in Fig. 2, from selected trials to formalized collaborations and gradual assumption of sponsor-investigator roles, reflects a deliberate capacity-building approach supported by an experienced research team.

Our mission is to further develop an integrated, oncology-focused clinical trial platform that supports both IIT and industry-sponsored studies, including innovative therapeutic programs such as personalized cancer vaccines. This initiative is designed to foster translational research by bridging the gap between discovery and practical application, enabling patients to access cutting-edge therapies within the private healthcare setting. Central to this strategy, the CTU functions as both a sponsor office and operational hub, alongside a personalized vaccination program, which collectively provide the structural and operational backbone for clinical innovation within the private healthcare setting to complement existing standard-of-care treatments. Establishing such a platform requires a sophisticated, patient-centered operation built on three pillars: a deep commitment to trust, an agile regulatory capability able to navigate both industry and investigator-driven trials, and the ability to forge coordinated partnerships. No single entity can deliver a personalized vaccine trial independently, and success depends on tightly integrated external collaborations, while the clinic's central role in patient care positions it to contribute meaningfully to both scientific output and potential downstream benefits.

Nowhere is the impact of these pillars more evident than in the development and execution of a personalized cancer vaccine trial. Personalized cancer vaccines represent a promising next generation of immuno-oncology therapies, tailored to the unique profile of each patient's tumor and embodying the future direction of individualized cancer treatment [43–45]. The significant investment in these programs at such an early stage, together with the engagement of leading pharmaceutical companies, underscores the broad industry enthusiasm for this emerging modality [2]. Early clinical trials have demonstrated safety, feasibility, and encouraging efficacy, reinforcing the potential for these therapies to be integrated into standard clinical practice [46, 47]. Moving from theory to practice, the modern personalized cancer vaccine trial serves as the ultimate case study, stress-testing every component of a private clinic's research infrastructure. These are not simple "drug A vs. drug B" studies; they are complex, patient-specific manufacturing and treatment processes that push the boundaries of logistics, patient care, regulation, and collaboration. A clinic that can successfully participate in, or even lead, such a trial demonstrates the highest level of research maturity.

Implementing these vaccines requires careful orchestration of scientific, regulatory, and logistical expertise (Fig. 3). The process begins with surgical biopsy and transport of the patient's tumor tissue under strict, temperature-controlled conditions, followed by next-generation sequencing of the tumor and normal DNA to identify unique cancer mutations, or neoantigens. Advanced computational algorithms predict which neoantigens are most likely to elicit a strong immune response, and a bespoke vaccine is then manufactured according to GMP standards, tailored for each individual patient. The final product must be delivered back to the

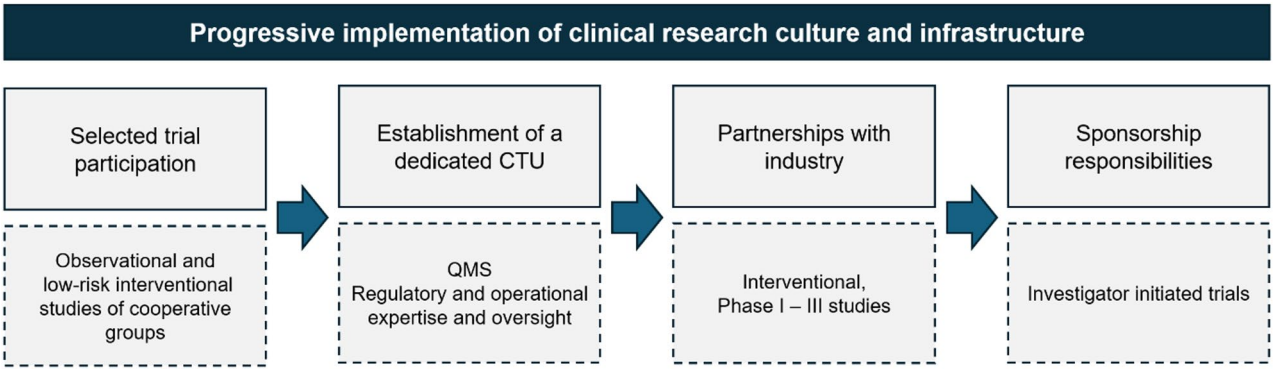

Fig. 2 Stepwise strategy for developing clinical research capacity. Institutions wishing to initiate clinical trials and establish a clinical research culture and infrastructure may begin with selected trial participation through established cooperative groups such as the Swiss Cancer Institute (SCI, Switzerland), the European Organisation for Research and Treatment of Cancer (EORTC), or the Alliance for Clinical Trials in Oncology (United States). The establishment of a dedicated Clinical Trials Unit (CTU) and a quality management system provides expertise, support and a structured framework for clinical research activities. With this framework, institutions can build trusted partnerships with industry and participate in more complex interventional studies, ranging from Phase I to III. Institutions with sufficient experience may subsequently assume sponsorship responsibilities and initiate investigator-initiated trials, reflecting a gradual expansion across the full spectrum of clinical research capabilities

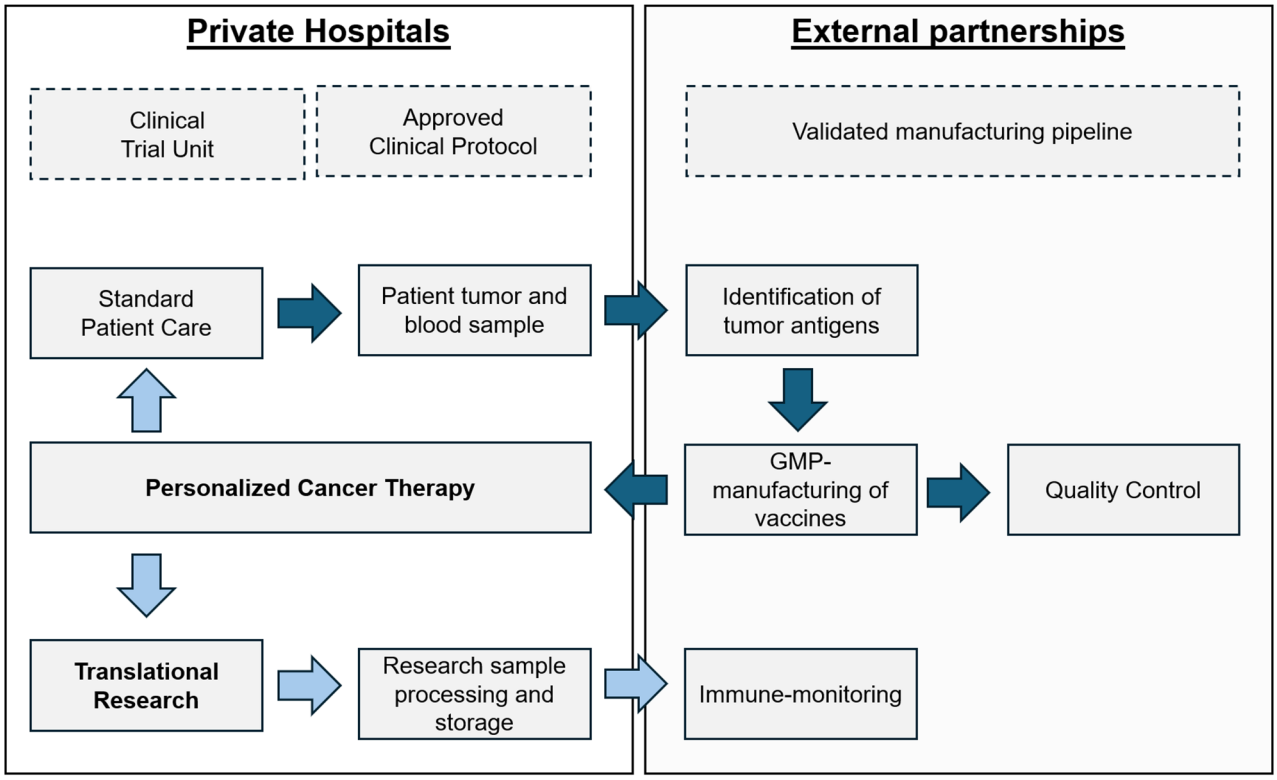

Fig. 3 Framework for implementing personalized cancer vaccines in private clinics. The clinical trial unit oversees vaccine development, ensuring ethics approval and compliance with regulatory authorities (e.g., Swissmedic). It coordinates with GMP-compliant partners for vaccine production and integrates translational research to enhance patient care. This framework illustrates how clinical trials and research activities can be implemented into routine practice to efficiently translate innovations from bench to bedside to be part of patient's standard-of-care treatment

clinic with precise timing for administration, creating a multi-week, high-stakes logistical chain in which any disruption can compromise both the therapy and the patient's opportunity for benefit. The financial, personnel, and infrastructure investment required, from ultra-low temperature freezers to certified laboratory space and specialized training, is substantial, yet the strategic return is equally significant. A clinic capable of delivering this level of care is immediately recognized as a cutting-edge center of excellence, attracting patients, clinical talent, and collaborative opportunities, while establishing its leadership in personalized medicine.

While the CTU provides the in-house expertise to lead the scientific and regulatory aspects of the project, built upon our own concept and strategic vision for personalized therapies, the production and manufacturing of the vaccines rely on collaboration with both local and international GMP-compliant partners. Some academic structures may have these facilities in-house, but private hospitals typically need to establish partnerships to access GMP-compliant manufacturing, with the added complexity that regulatory standards vary across regions, such as between Europe, the U.S., and Canada [48]. The CTU coordinates these partners while designing and authoring the clinical protocols in-house, in close collaboration with the principal investigators. It ensures rigorous quality control, compliance with Swissmedic and Ethics Committee requirements, and adherence to procedures that prioritize patient safety, thereby guaranteeing the effective and safe delivery of vaccines. Such a trial exemplifies the transformative potential of a truly integrated clinical research platform, requiring seamless coordination from tumor biopsy to the delivery of a bespoke therapy. At the same time, these trials impose heightened patient-centric demands that surpass those of conventional studies. Patients rely on the research team, particularly nurses, to guide them through a complex, often anxiety-inducing process. The team must provide clear education about the scientific underpinnings of the therapy to ensure informed consent, coordinate the intricate sequence of biopsies, blood draws, and vaccine administration, and offer emotional support throughout the "manufacturing window" while patients await their individualized therapy. This high-touch approach is particularly suited to private clinics, where existing physician-patient relationships can be leveraged to foster trust and engagement. Successfully managing this process not only ensures patient safety and adherence but also strengthens loyalty and reinforces the clinic's reputation for compassionate, state-of-the-art care.

Personalized cancer therapies also bring unique challenges, including regulatory complexity, high infrastructure demands, and cost considerations [49]. From an ethical and regulatory perspective, private hospitals must adhere to the same standards as any research institution: all studies are reviewed and approved by ethics committees and regulatory authorities, and patient enrollment is governed by predefined clinical inclusion and exclusion criteria, rather than financial factors, and trials are registered in public registries such as ClinicalTrials.gov or national registries like Human Research Switzerland (HumRes) to ensure transparency. Moreover, timely publication of trial results, including negative findings, should be encouraged to support scientific rigor and open access to knowledge. While these institutions operate on a for-profit basis, this does not alter the ethical or regulatory framework. As in academic centers or industry-sponsored trials, robust sponsor oversight and transparent management of potential conflicts of interest through procedural separation of roles, disclosure mechanisms, and independent monitoring, are essential. Data privacy and ownership must be rigorously protected, particularly given the large volumes of sensitive patient information involved in personalized therapies. Clear separation between scientific and commercial oversight further reinforces ethical integrity and public trust in privately conducted research. Notably, private hospitals can play a positive role in expanding access to clinical studies, offering diverse patient populations the opportunity to participate in innovative therapies. Transparency, rigorous adherence to ethical guidelines, and careful governance remain critical to ensure that patient welfare and trial integrity are maintained across all settings.The production of individualized vaccines involves small-batch manufacturing, intensive quality testing, and often relies on individualized artificial intelligence (AI)-driven antigen selection, all of which require specialized expertise and close oversight. As AI-based methodologies are becoming increasingly common in clinical trial protocols and investigational product manufacturing steps, regulatory agencies have raised concerns about their validation and oversight, as reflected in recently published guidelines. For example, the FDA issued its draft guidance for the use of AI to support regulatory decision-making [50], which outlines a risk-based framework for defining the context of use, validating AI models, and ensuring their credibility in drug development. Similarly, the EMA released a reflection paper on the use of AI in the medicinal product lifecycle [51], which sets out principles for transparency, traceability, and governance of AI tools across clinical development and the product lifecycle. Despite these hurdles, a carefully designed CTU and structured collaboration network can overcome these barriers, demonstrating that such initiatives are feasible in a private clinic setting. Ultimately, the successful implementation of personalized cancer vaccines in a private clinic not only expands access to innovative therapies for local patients but also attracts international participants, enhancing the clinic's reputation as a center of excellence in translational medicine. Taken together, with strategic investment, expertise, and robust infrastructure, private healthcare institutions can play a pivotal role in advancing personalized medicine and delivering tangible benefits to patients.

Ultimately, personalized vaccine trials represent the convergence of all the key challenges and opportunities in modern clinical research. For a private clinic, the ability to execute such trials represents the highest expression of operational sophistication, patient-centered care, regulatory mastery, and collaborative acumen. Successfully navigating this complex ecosystem is a definitive statement of its capabilities and its commitment to the future of medicine.

Future perspectives

As healthcare systems evolve toward more personalized, data-driven models of care, private hospitals are uniquely positioned to become agile hubs of translational research. Their operational flexibility, proximity to patients, and capacity for rapid decision-making allow them to bridge the gap between scientific innovation and real-world application. To fully realize this potential, the next phase of development must move beyond pilot projects and isolated initiatives toward a coordinated, strategically designed research ecosystem. The CTU can serve as critical enablers by supporting physicians in regulatory navigation, protocol development, and operational oversight, thereby lowering the barriers for private practitioners to engage in research. Sustaining this transformation will also require investment in robust research structures, advanced digital tools to support data management and trial oversight, and the strategic engagement of external partners or consultants to provide specialized expertise. Digital innovation is set to further amplify the role of private hospitals in clinical research. The integration of EHRs into structured feasibility assessments will significantly improve patient identification and streamline recruitment processes, while AI-driven algorithms increasingly support patient stratification, biomarker discovery, and adaptive trial design. In addition, with the emergence of decentralized trial models, remote monitoring tools, telemedicine, and secure digital platforms open new opportunities for private hospitals to expand patient access and participation. These advances will allow private hospitals to participate in complex, multicenter studies while generating high-quality, patient-centric data that meets the expectations of regulators and sponsors.

Table 1 Summary of key features between academic institutions and private hospitals in clinical research

	Academic institutions	Private hospitals	Strategic implication for private hospitals
Organizational structure	Large, complex, and often bureaucratically structured. Layered approvals and formal "invitation to tender" procedures are often required.	Leaner and more focused, leadership can directly drive research initiative without procedural constraints.	**Operational efficiency is maximized**: allows for rapid implementation of strategic initiatives and efficient resource allocation, reducing administrative overhead.
Clinical operations	Rely on large, established research departments with dedicated, full-time staff across numerous specialized roles	Requires deliberate investment to build a lean, multidisciplinary CTU. Employs a core team and strategically outsources specialized functions to external partners and consultants	**High degree of operational and financial flexibility**. Outsourcing enables access to world-class expertise, allowing private hospitals to scale its capabilities as needed
Speed of trial activation	Significantly longer time required for budget and contract negotiation and revision	Can be substantially faster, enable by streamlined administrative procedures and agile decision making	**Speed is a key advantage**, making private hospitals attractive partners for industry sponsors aiming to accelerate development and reduce time-to-market
Physician-patient relationship	Interactions are structured and protocol-focused, with less emphasis on long-term physician–patient continuity	Recruitment leverages strong, pre-existing patient-physician trust and relationships	**Hospitality-driven care model** drives higher enrollment and stronger long-term patient retention, generating a reputational halo
Funding and sponsor model	A mix of public grants, institutional funds, and industry sponsorship. Often acts as the Sponsor-Investigator for "bench-to-bedside" Investigator-Initiated Trials (IITs)	Primarily funded by industry-sponsored trials, providing direct revenue, but increasingly taking on the Sponsor-Investigator role for innovative programs	**Offers a direct and diversified revenue stream**, **p**ositioning the hospital as a reliable operational partner for industry, with the potential to evolve into a center of innovation
Key challenges	Overcoming institutional "friction," including slow bureaucracy and protracted negotiations. Managing intra-institutional competition for resources and navigating complex internal politics	Securing significant upfront capital investment for infrastructure and personnel. Building a research culture and navigating complex regulatory requirements	**Challenges are primarily front-loaded and financial.** A well-structured business plan with a phased implementation strategy is critical to mitigate risk, demonstrate early wins, and ensure long-term sustainability and profitability

Future efforts should focus on strengthening collaboration across multiple levels to maximize the impact of private hospitals in clinical research. Engagement must begin with individual physicians, whose participation is essential for driving innovation in private practice. Beyond this, partnerships with both academic institutions and industry can provide methodological rigor, regulatory expertise, and access to emerging technologies. Equally important is the development of stronger cooperation within networks of private clinics. While many clinics still operate independently, pooling patient populations and harmonizing standards across sites is particularly critical for rare diseases and highly specialized indications, where recruitment challenges often limit feasibility. In oncology, in particular, such platforms can ensure that even highly personalized therapies become accessible to a broader spectrum of patients, positioning private hospitals as key contributors to national and international clinical research initiatives.

Ultimately, private clinics should be seen not just as new entrants, but as reliable, complementary partners within the broader clinical research ecosystem. This effort may be reinforced by a strong commitment to "academize" clinical research practices in the private setting and the ability to harness the collective power of clinic networks. Several domains, such as precision oncology, AI-driven personalized medicine, molecular diagnostics, and theranostics, are already emerging as forward-looking areas of excellence. By leveraging this momentum, private hospitals place themselves at the forefront of progress, bridging the strengths of private healthcare with the standards and ambitions of academic medicine.

Conclusions

Private hospitals are a promising frontier for clinical research, capable of bridging innovation and patient care. With strategic investments in advanced digital infrastructures, trained personnel, and regulatory guidance, private institutions can position themselves as agile, patient-centered engines of translational research and implement complex clinical programs while maintaining rigorous quality standards. By leveraging existing resources and fostering collaboration with academic and industry partners, private hospitals can accelerate access to novel therapies and generate high-quality data. Properly structured, these initiatives benefit patients, advance translational medicine, and position private practices at the forefront of medical innovation (Table 1).

Abbreviations

ACT EU	Accelerating Clinical Trials in the European Union
AI	Artificial intellignece
CFR	Code of Federal Regulations
ClinO	Clinical Trials Ordinance
CRO	Contract Research Organization
CTA	Clinical Trial Application

CTR	Clinical Trials Regulation
CTU	Clinical trial unit
eCRF	Electronic case report form
EHDS	European Health Data Space
EHR	Electronic health record
EMA	European Medicines Agency
EORTC	European Organisation for Research and Treatment of Cancer
EU	European Union
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GMP	Good Manufacturing Practice
HIPAA	Health Insurance Portability and Accountability Act
HRA	Human Research Act
HumRes	Human Research Switzerland
ICH	International Council for Harmonisation
IIT	Investigator-initiated trial
IMP	Investigational medicinal product
IND	Investigational New Drug
IT	Information technology
IVDR	In Vitro Diagnostic Regulation
MDR	Medical Device Regulation
NHS	National Health Service
QMS	Quality management system
SCI	Swiss Cancer Institute
SOP	Standard operating procedure

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