



# Precision patient finding: The key to speed, savings, and trial success in biotech

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# Introduction

Finding the right patients to participate in clinical trials and research has long been a significant challenge for biotech companies. Inefficient patient finding processes not only impede the development of new treatments and their delivery to patients, but involve sky-high costs, multi-year timelines and the possibility of trial failure and termination due to insufficient recruitment and low data quality.

More than 100 million genomes are estimated to be sequenced by 2025, and adoption of EHRs in US hospitals grew from 9% in 2008 to 96% in 2021.<sup>1,2</sup> As the volume of genomic data and the adoption of electronic health records (EHRs) continues to grow year on year, it's never been more important for biotechs to invest in precision patient finding. Not only does this method take advantage of the huge volume of data being produced and its ability to enhance drug target identification and development, but it also serves to significantly reduce timelines, dramatically reduce costs, increase the chance of trial success, and ultimately deliver impactful treatments to patients, faster.

A 2022 study found that the average recruitment period for a Phase III clinical trial had increased by five months between 2011 and 2019 and that the median number of registered sites had also increased by more than 30% over a 12 year period.<sup>3</sup> The good news is that as technologies, digital systems, and data analysis tools evolve, there is a growing opportunity to match patients to relevant precision medicine and rare disease studies with increasing accuracy and efficiency.

In a world where people increasingly understand the power and importance of personal data, patient finding and recruitment has to go beyond the traditional approach to build trust, overcome data security concerns, and help



participants understand why and how their contribution makes a difference. The fact is that 85% of all clinical trials fail to recruit enough patients and 80% are delayed due to recruitment problems, suggesting a more efficient, more patient-centric approach is required to not only successfully develop new treatments but to significantly increase business efficiency and effective trial design.<sup>4</sup>

Traditional patient finding often takes a centralized approach with little input from patients, following a standardized formula with less emphasis on individual participant preferences and circumstances. By investing in approaches that utilize breakthrough technologies to narrow the pool of relevant patients and take into account their daily needs, concerns, and limitations, precision patient finding methods can increase the speed of recruitment and the chances of trial success. These methods rapidly reduce timelines and financial outlay.

# What is precision patient finding?

Precision patient finding is an evolving field that is growing in line with the demands of precision medicine and rare disease research. Unlike traditional patient recruitment methods, it harnesses technologies for data gathering and advanced analytics, and utilizes comprehensive patient data (including genomic profiles) to rapidly identify groups of patients who have an increased likelihood of study eligibility and enrollment. Here we'll explore some of the key elements of precision patient finding and how they interlink.



## Genetic and clinical profiling

Genetic and clinical profiling are core components of precision patient finding, enabling researchers to leverage detailed, comprehensive datasets to identify highly relevant patients and match them with appropriate research opportunities.

This advanced profiling involves using electronic health records, genetic data (whether through providing sequencing or making use of pre-existing genetic data) and lifestyle factors to rapidly establish if a patient is or is not a likely fit for a given study.<sup>5</sup> Not only does this help reduce the cost and timeline of patient finding, but it helps identify the individuals who are most likely to benefit from the outcomes of the research.

## Advanced data analytics and artificial intelligence

Artificial intelligence (AI) assisted patient finding and trial matching has the potential to sift vast volumes of patient information, including genetic data and EHRs, to identify relevant individuals based on specific eligibility criteria. Such technologies enable identification of highly relevant patients at a speed which is not achievable with a manual, labor-intensive approach. Vivaly, these technologies also enable a high level of accuracy when it comes to patient selection, trial matching, and enrollment. For example, an Australian study published in 2020 was able to demonstrate a 91.6% accuracy for overall eligibility assessment for a lung cancer clinical trial when using AI technologies to identify patients.<sup>6</sup>

AI is also helping to power tailored recruitment strategies by using predictive analytics to forecast behaviors, treatment responses and potential risks, contributing to creating trials which ensure higher levels of safety, efficiency and reduced risk of human error.<sup>7</sup> For example, AI analytics softwares are able to identify high-risk patients who may be

susceptible to complications (such as comorbidities or interaction of medications), and who are therefore unsuitable for participation despite initially appearing to be a good match with eligibility criteria.<sup>8</sup>

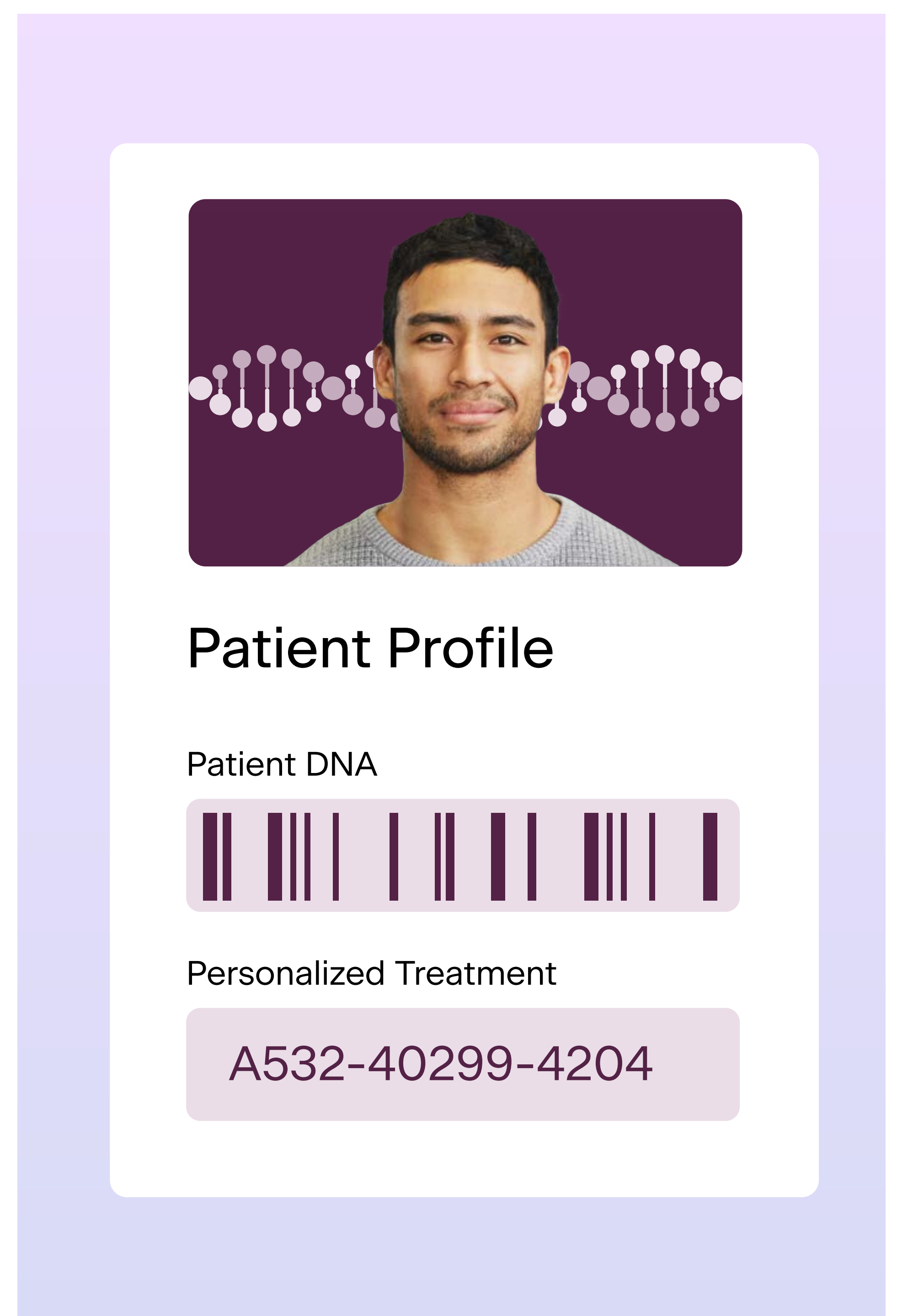
### Patient registries and databases

Patient registries collect standardized information and patient data on specific diseases and conditions (such as the American Heart Association's Get With The Guidelines registries).<sup>9,10</sup> Registries often include information such as medical history, lifestyle data, treatment plans and patient outcomes.<sup>11</sup>

Access to patient registries represents a key component of precision patient finding, as these databases provide a source of systematically collected, uniformly formatted data. Such data is highly searchable and ideal for the application of AI-assisted analytics queries. The systematized, longitudinal nature of patient registries provides high-quality, reliable data points which enable increased accuracy and efficiency when it comes to patient identification and clinical trial matching. Some registries even include real-time or near real-time updates so that, when new information about a patient becomes available, the entry in the registry can be updated immediately - once more contributing to the accuracy of patient-finding efforts. ...

### Partnerships with healthcare providers and advocacy groups

Now more than ever, healthcare providers (HCPs) and patient advocacy groups play a vital role in precision patient finding programs. Such groups provide a direct connection with large networks of patients living with specific conditions and who are highly motivated to support research efforts - as patients stand to directly benefit from therapeutic advances.



The graphic illustrates a patient profile within a light purple frame. At the top is a portrait of a man with a DNA double helix overlaid. Below the portrait is the title 'Patient Profile'. Underneath, there is a section for 'Patient DNA' with a barcode-like representation. Below that is a section for 'Personalized Treatment' with a rounded rectangular box containing the alphanumeric string 'A532-40299-4204'.



**Access to patient registries represents a key component of precision patient finding, as these databases provide a source of systematically collected, uniformly formatted data. Such data is highly searchable and ideal for the application of AI-assisted analytics queries.**

HCPs and advocacy groups can directly raise awareness of clinical trial opportunities with a high degree of efficacy and impact, as they represent trusted voices within patient communities. These voices are vital for increasing understanding of the benefits and potential of clinical trials, as well as willingness to participate and share data with researchers.

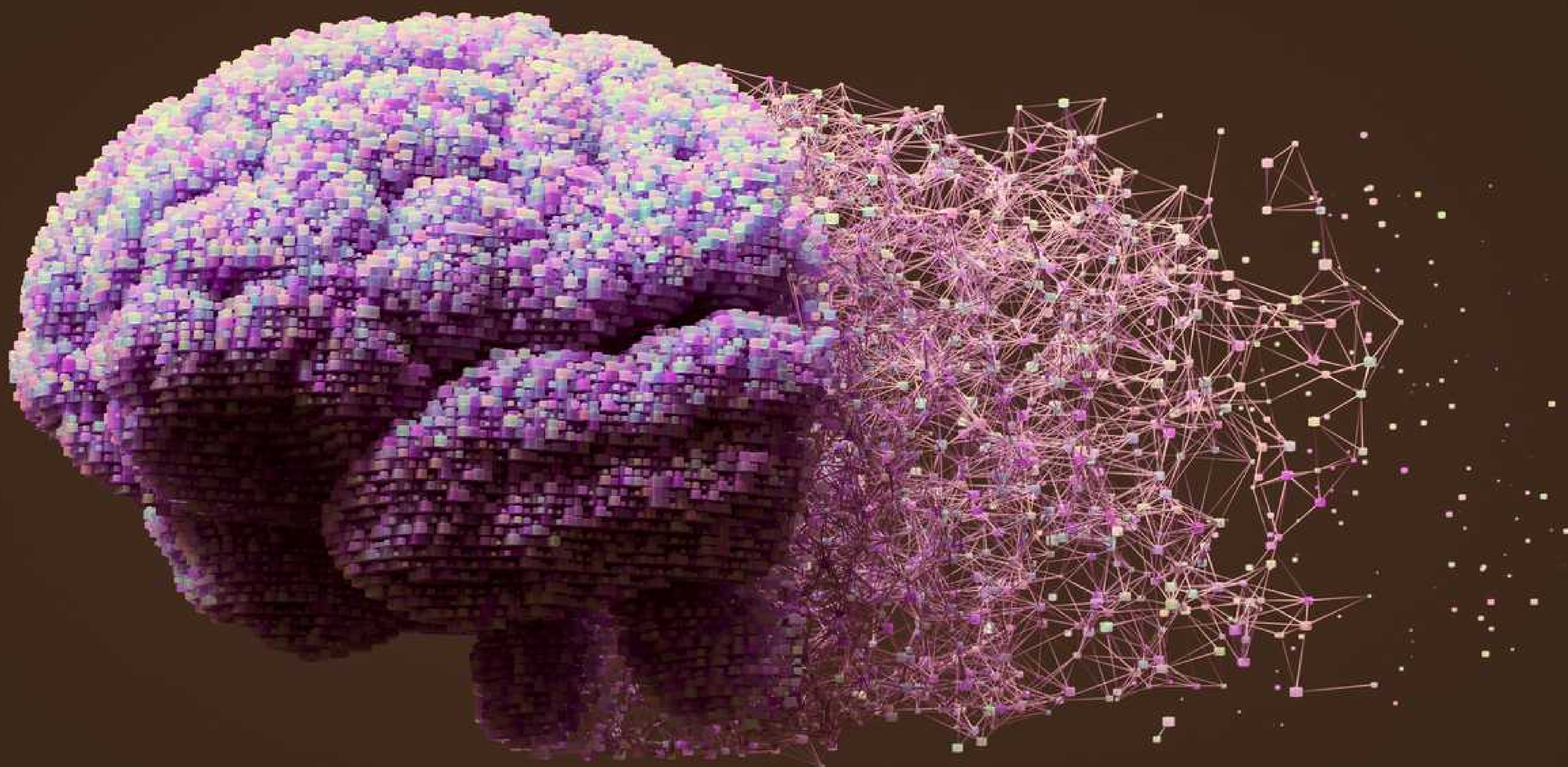
The contribution of patient advocacy groups also helps to reduce trial termination and drop out rates, as patient-informed recruitment and trial design take into account the specific needs of individual communities. A 2018 meta-analysis of 26 studies found that public and patient involvement “modestly but significantly increased the odds of participant enrollment” in clinical trials, especially in those that included input from people with lived experience of the relevant condition.<sup>12</sup>

Importantly, such partnerships also support diversity of recruitment, helping to increase

enrollment of individuals from underrepresented and marginalized communities and populations, ensuring they are effectively represented in clinical trials and research.<sup>13</sup>

## Disrupting “traditional” approaches

Precision patient finding is disrupting traditional recruitment approaches by leveraging new analytics technologies, unified data repositories, and partnerships with advocacy organizations to create a decentralized approach that streamlines patient finding efforts. Combined, these factors create a process that is not only significantly faster and more cost effective, but which also offers a high degree of efficiency and accuracy, increased patient engagement, and reduced chances of trial failure or termination.



# Precision patient finding helps biotechs move faster

Using the approaches we have just explored, precision patient finding techniques can help biotech companies to move faster, enabling them to rapidly identify relevant patients and dramatically reduce the time and costs involved in running a successful clinical trial.

Through leveraging data, technology, and partnerships to identify specific patient populations, biotechs are not only able to increase the speed and efficiency of trials but improve the participant experience, reduce risk to patients and, potentially, get treatments to market faster.

## Case study: Owlstone Medical

Sano Genetics worked with Owlstone Medical to deploy precision patient finding techniques to support the development of a breath test which can better predict individual response to medication compared to using genetic data alone.

This required identifying patients with rare genetic variants present in only ~1-3% of the population. Using its systematized patient registry, Sano was able to rapidly identify relevant pre-genotyped individuals from a database of more than a million people and screen them for eligibility using an at-home digital survey. Additionally, Sano coordinated and deployed telemedicine approaches to carry out an over-the-phone prescreen, meaning that only qualified patients were required to attend an in-person lab visit.

By utilizing databases, digital technologies, and telemedicine, Sano was able to deliver the relevant patients at a radically reduced cost within a period of just six weeks. In contrast, traditional patient finding approaches projected the process would take six to 12 months to complete, at ten times the cost.



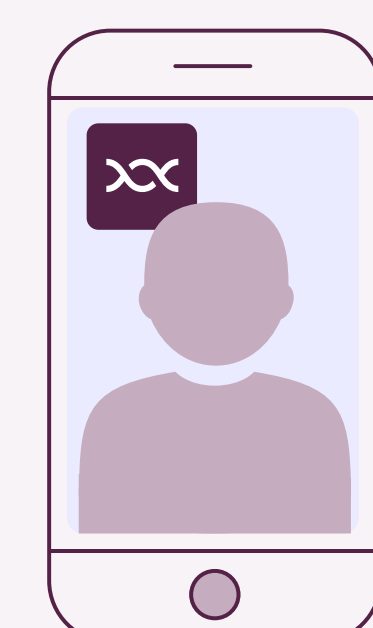
Recruit volunteers with rare genetic variants present in ~1-3% of people

Arrange for qualified individuals to attend an in-person lab visit in London



Screen users through a survey on the Sano Genetics website

Handle expenses of attendees, coordinate and carry out phone call prescreen





# The financial impact of precision patient finding programs

Precision patient finding has the potential to radically reduce the cost of trials and create a more centralized approach which serves to benefit a multitude of stakeholders, from biotechs to HCPs and patients.

## Comprehensive genome profiling

One approach that has high cost-saving potential is comprehensive genome profiling (CGP). In the majority of genetics-based clinical trials, potential participants are genetically sequenced to verify the presence of a single specific variant and the results are then retained by the sponsor or relevant participating institution. Often, the reason single gene tests are employed is due to regulatory requirements.

Using a genetic screening test that costs \$500 per person to screen for a variant present in one out of 100 people, a clinical trial requiring 20 eligible participants would need a sequencing budget of \$1 million. If 10 trials each require 20 participants that carry a genetic variant present in 1% of the population, and each trial uses an individual, biomarker

specific test, the total screening costs for those studies will be \$10 million (the cost of 20,000 tests).

However, if all ten biomarkers could be covered in a single comprehensive genome profiling test, this means that 10x fewer tests (only 2,000) would be required for all of the trials to identify 20 eligible patients. Therefore, if a CPG test costs \$2,500 per person, the total screening costs for those 10 studies would be \$5 million – half that of a traditional single variant approach.

In trials where speed is the priority rather than cost saving, the same \$10 million screening budget could be used to sequence 4,000 patients, enabling identification of eligible patients twice as fast and halving the time required to complete trial enrollment.<sup>14</sup>

## Reducing trial delays

In a 2023 analysis of 2,542 randomized clinical trials registered on ClinicalTrials.gov, researchers found that approximately one in five studies were completed within the planned time frame and that the median trial delay was 12.2 months.<sup>15</sup> With the average daily cost of running a clinical trial estimated to be approximately \$40,000, that works out as the average clinical trial losing more than \$17 million to delays alone. However, it's important to note that this figure varies significantly depending on the disease area of focus and the stage of the clinical trial.<sup>16</sup>

For instance, the average daily trial costs by phase are as follows:

- **Phase III: \$55,716 per day**
- **Phase II: \$23,737 per day**
- **Phase IV: \$14,091 per day**
- **Phase I: \$7,829 per day**

Precision patient finding methods such as CGP therefore not only help reduce the cost of screening and make more efficient use of resources and operational budgets, but also have a wider impact on trial costs. Such methods also contribute to a reduction in delays through rapid identification of highly relevant participants, enhanced enrollment efficiency and reduced numbers of screening failures. When tools such as genomic profiling and AI data analysis are brought together, this helps generate a highly relevant pool of patients from the outset and reduces the number of individuals who screen fail at cost to the sponsor.

These technologies can also help reduce delays associated with underperforming trial sites by identifying locations that have higher concentrations of eligible patients, enabling sponsors to focus trial recruitment efforts more effectively.<sup>17</sup>



## Minimizing dropout through better trial matching

Losing patients to trial drop out is also a costly process. When recruiting a single patient can cost more than \$6,500, replacing them can then cost even more.<sup>18</sup> Reducing patient dropout is a key area in which biotechs can make cost and time savings. The use of analytics and patient profiling is fundamental to helping reduce dropout, enabling the identification and exclusion of patients who, for example, live too far from trial sites or whose stage of disease means participation is impractical.

Precision patient finding approaches can also minimize dropout by identifying highly relevant patients from the outset, in turn resulting in a better quality patient experience and a more positive view of trial participation.



## Reducing the risk of trial failure

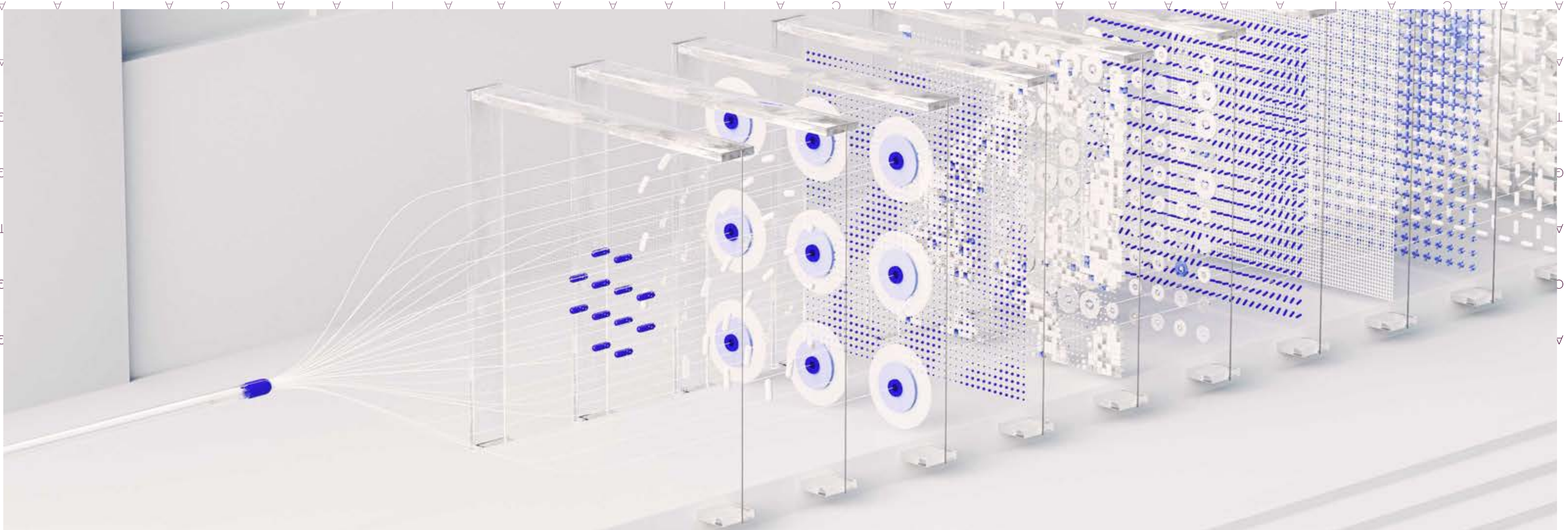
Reducing the risk of trial failure is a fundamental objective of precision patient finding programs in a highly competitive sector where the overall success rate of clinical trials is only 7.9%.<sup>19</sup>

The approaches discussed above play a key role in helping de-risk trials and enabling the dynamic adaptation of trial design as the study progresses. When these methods are used to identify highly relevant patients from the outset, insufficient enrollment, high screen fail rates, and patient drop-out are significantly reduced, leading to an overall reduced risk of trial failure.

Additionally, enhanced accuracy in patient selection leads to overall better quality of trial data, resulting in enhanced patient outcomes and a greater chance of therapeutic success within a reduced timeframe.

# Technologies and tools enabling precision patient finding

There are a number of innovative tools and technologies which are enabling precision patient finding. From AI to e-consent, here we explore how they are changing the face of the clinical trial landscape.

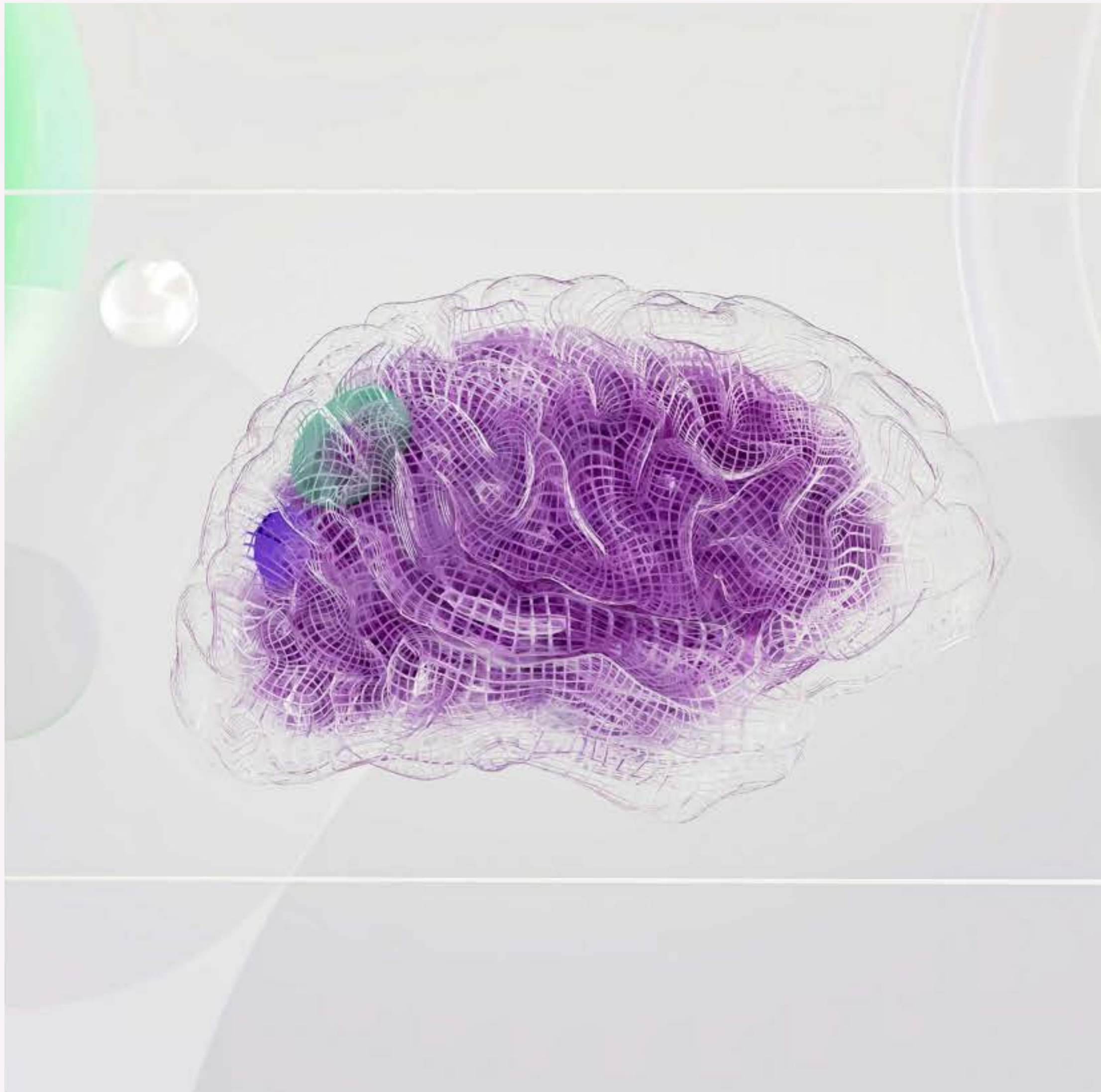


## Artificial intelligence and machine learning

AI and predictive modeling tools can be applied to patient data to predict clinical outcomes and responses to investigational treatments using a combination of lifestyle data, EHRs, genomic data, and more.<sup>20</sup> These models can assist clinicians in selecting participants who are more likely to benefit from the treatment or, conversely, experience adverse effects.

As patient recruitment can take up to one-third of a study timeline, creating optimizations using AI tools can have a significant impact on the time it takes for new therapies to reach patients.<sup>21</sup> For example, in one study, an AI analysis system was applied to a clinical trial for a new lung cancer treatment with the aim of assessing how adjusting the criteria for participation impacted patient risk and safety. The researchers found that the AI system was able to suggest adjustments that would double the number of eligible participants without increasing risk to patients.<sup>21</sup>

Applying AI and machine learning (ML) models can help produce study criteria that optimize the chances of reaching enrollment goals while ensuring patient safety and cutting time to market. However, it is vital that such models are applied to high-quality, standardized and accurate datasets so that the outputs are representative of real world patient populations and do not produce misleading results.



## Real-time data integration

Real-time data integration involves near instantaneous updating and processing of data and minimizing the delay between data generation and its availability for use. Unlike traditional batch processing, which collects and processes data periodically in predefined chunks, real-time integration operates on a nearly immediate basis. In the context of clinical trials and patient finding, real-time integration theoretically enables instant analysis of the latest genomic data and EHRs to identify relevant patients and increase understanding of treatment responses and health outcomes.<sup>22</sup>

## Integration of multiple sources

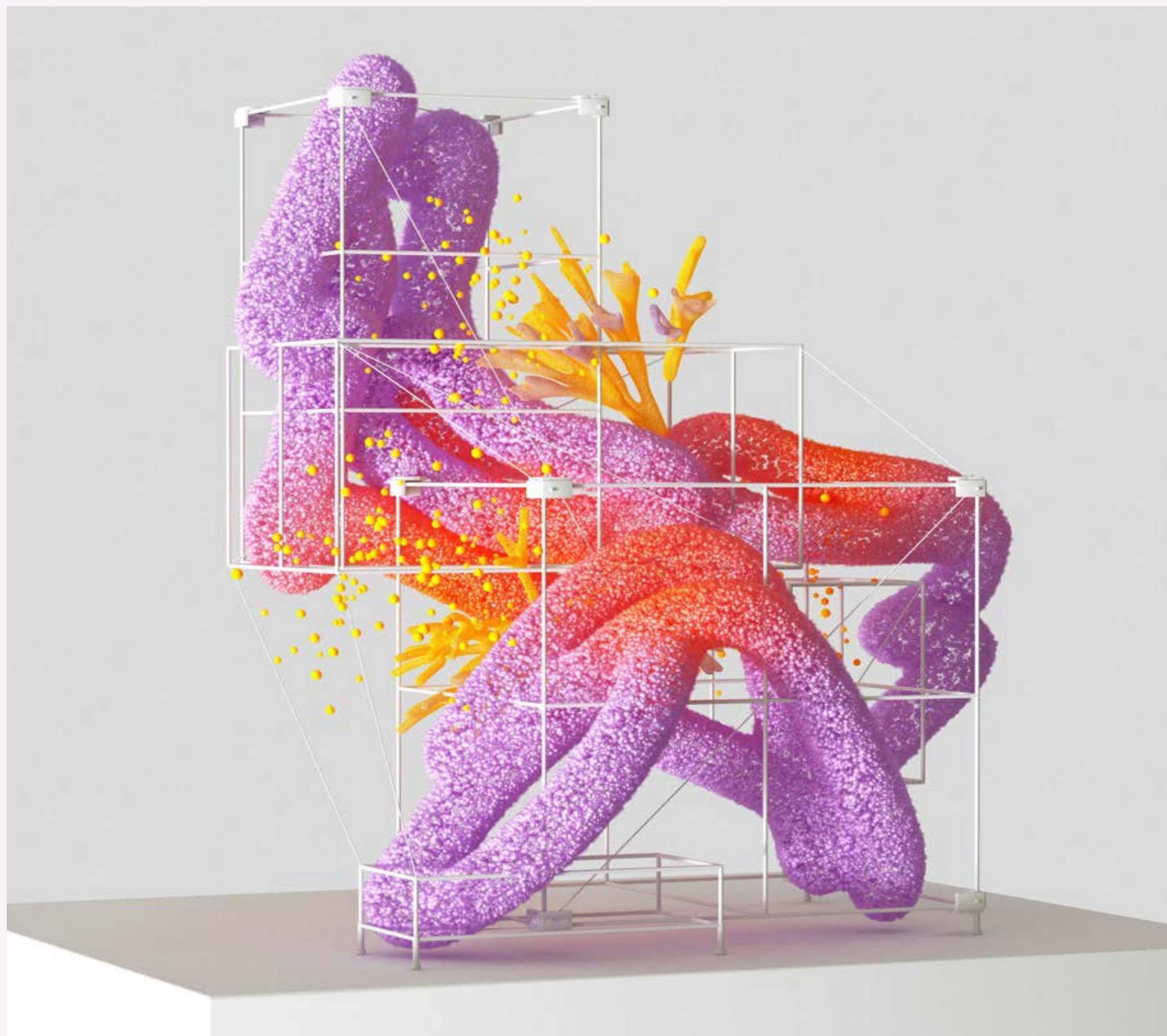
This type of integration also combines data from multiple sources to provide a comprehensive overview of a patient, their eligibility criteria, and progress in the screening and enrollment process. Ultimately this leads to enhanced decision making and an improved patient experience, not only during initial screening and enrollment, but throughout the entire clinical trial.<sup>23</sup> However, it is vital that the relevant sources are formatted in such a way that interoperability and functionality enables both seamless and secure access and analysis. Such vast, comprehensive datasets must always protect patient anonymity and be compliant with HIPAA and other relevant data security regulations.<sup>24</sup>

## Increased safety

Access to such up-to-the-minute data also enhances patient safety, enabling dynamic decision making regarding a patient's eligibility and offering a clear overview of interconnected factors which may impact an individual's risk and response to a novel therapeutic.<sup>25</sup>

## Genomic data analysis

Collection and analysis of genomic data is playing a key role in transforming how patients are matched to clinical trials and research opportunities. Use of genomic data enables more precise patient stratification, helping identify patients with rare genetic variants and enabling trial and therapy matching based on genetic characteristics.



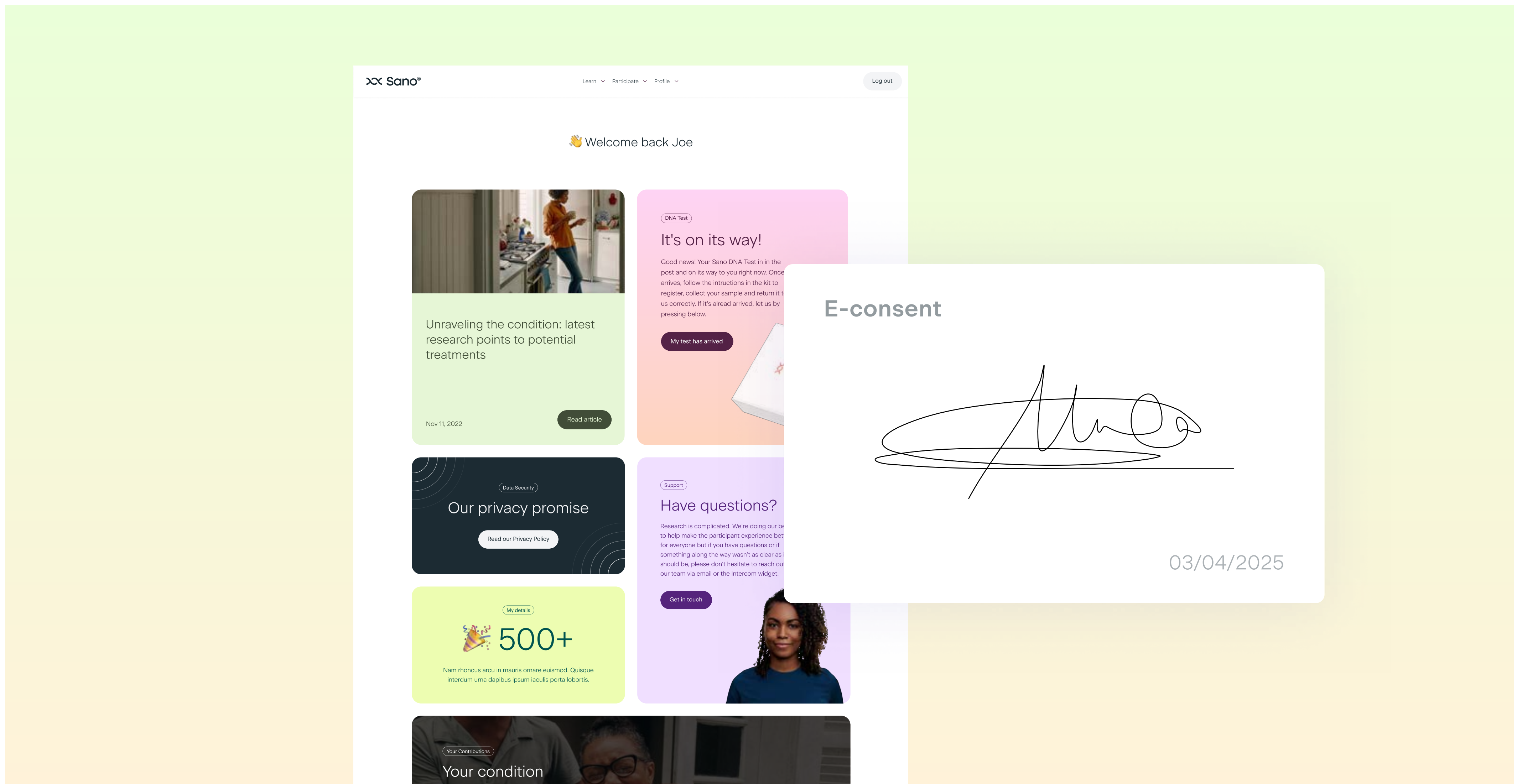
## Recontacting for future studies

Participation in genomic testing and genetic counseling initiatives allows for the possibility of recontacting patients—with their consent—for future research that leverages their existing genetic data.<sup>26</sup> Patients who agree to be recontacted based on their genomic profiles significantly contribute to reducing the costs associated with patient finding. This approach also substantially shortens trial timelines, as suitable patients can be identified using existing genetic information without the need for additional genetic screening.

## Comprehensive screening

The cost of whole genome sequencing (WGS) has also dropped dramatically since the publication of the first human genome in 2003 – from an estimated \$2.7 billion to around \$600 in 2024.<sup>27</sup> With speed of delivery increasing rapidly and the cost of this type of genetic test decreasing, offering WGS to patients is becoming more accessible than ever before. WGS also reduces the need for each individual trial and organization to shoulder the cost of running single gene, panel, or exome screening, providing a comprehensive overview of a patient's entire genome with a single, one-off test.

If shared and securely stored in a centralized database (where it can also be integrated with EHRs), this data can significantly reduce cost of patient finding by providing enhanced stratification which enables rapid identification of highly relevant patients.



## Patient engagement platforms and e-consent technologies

Digital platforms and e-consent tools are also contributing to precision patient finding efforts, enabling either partial or complete from-home screening and participation.

Online e-consent not only streamlines the consent and enrollment process, but reduces barriers to entry for eligible participants. Time commitment and the need to travel are frequently cited as some of the biggest concerns and blockers for patients when it comes to participating in clinical trials.<sup>28</sup> E-consent removes the need for complex paperwork distribution and management and provides a centralized, easy-to-follow process which patients can complete from home at their convenience.

Digital participation platforms provide a single source of knowledge for participants throughout a trial, where they can check for updates, next steps, and access educational information to understand their contribution and its impact - ultimately helping to reduce drop-out. For example, less than 1% of participants who join a Sano Virtual Waiting Room drop out, compared to the industry average drop-out rate of 30%.<sup>29</sup>

These tools help to deliver a unified, high-quality patient experience and a space where participants can easily direct their questions and queries to the study team. Collectively they combine to provide an easy-to-use digital interface and single source of truth for participants, serving to build trust and enable timely communication, which in turn contributes to reduced risk of drop-outs and trial failure.



# The role of partnerships in precision patient finding

## Public-private partnerships and patient engagement

Public-private partnerships (PPPs) play a critical role in precision medicine by enabling expanded access and outreach to relevant patients, particularly underrepresented populations that private organizations often struggle to reach. Such partnerships have the power to expand and improve healthcare access by delivering genetic testing and personalized treatments to a larger number of patients, thereby increasing clinical trial participation in precision medicine studies. They also offer sustainable returns for biotech companies and other private sector entities involved in precision medicine without compromising cost-effectiveness within the public sector.<sup>30</sup>

Additionally, multi-sector partnerships lead to more informed patient engagement strategies and pooled knowledge when it comes to outreach in specific condition areas and rare disease subgroups—key focus areas in precision medicine. By collaborating across sectors, stakeholders can better understand genetic variations and biomarkers, enhancing the development of targeted therapies.

## Collaboration examples

There are a number of successful cross-sector partnerships that have been established with the aim of transforming and optimizing drug development processes in precision medicine through collaboration and resource sharing.

### The Innovative Medicines Initiative (IMI)<sup>31</sup>

Launched in 2008, the IMI aims to drive the development of new medicines, particularly in the field of precision medicine. Formed between the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Union (EU), its projects operate in four key areas:

- **Tackling complex diseases:** Focusing on conditions where precision medicine approaches and precompetitive collaborations are necessary.
- **Accelerating disease understanding:** Advancing knowledge to the point of personalized product development.
- **Providing digital platforms:** Creating shared resources where private and public organizations can pool data to improve precision drug development.
- **Addressing development gaps:** Identifying and filling gaps in drug targeting and development processes relevant to precision medicine.

As of 2021, the partnership had funded 144 projects with more than 3,000 participants and a budget of €5.3 billion, significantly contributing to advancements in precision medicine.

### Coalition Against Major Diseases (CAMD)<sup>32</sup>

Launched in 2009, CAMD was initiated by the Critical Path Institute (C-Path) in collaboration with the Engelberg Center for Health Care Reform at the Brookings Institution. Its goal is to transform drug development for neurodegenerative diseases through precision medicine approaches. Members include six nonprofit patient advocacy groups, 15 pharmaceutical companies, the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), the National Institute on Aging (NIA), and the National Institute of Neurological Disorders and Stroke (NINDS). By focusing on genetic and molecular markers, CAMD facilitates the development of targeted therapies for conditions like Alzheimer's and Parkinson's disease.

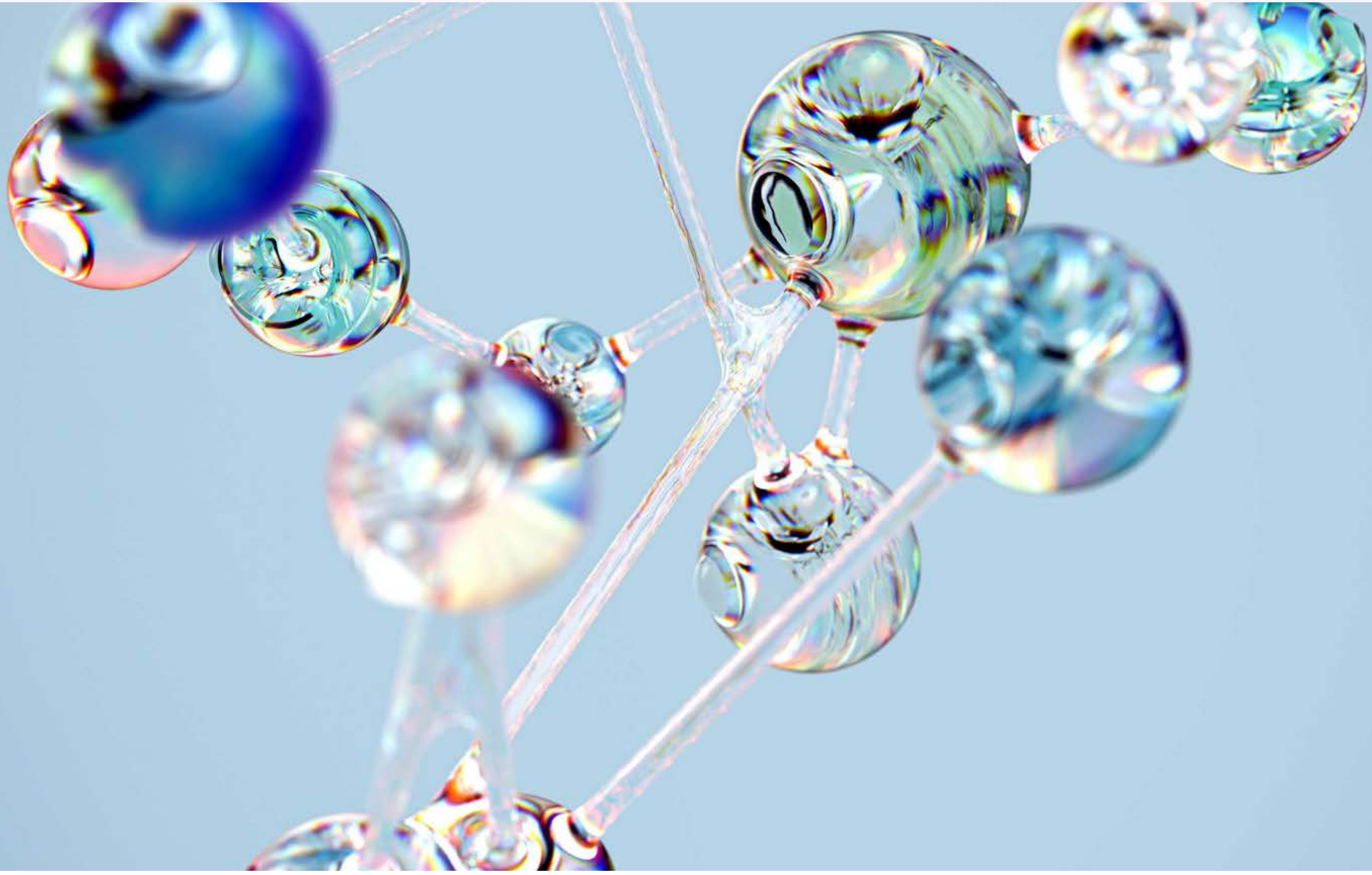
### **Accelerating Medicines Partnership (AMP)<sup>33</sup>**

AMP is a public-private partnership between the National Institutes of Health (NIH), the FDA, multiple biotech and pharmaceutical companies, and other nonprofit organizations. The collaboration aims to transform the current diagnostic and therapeutic development process by emphasizing precision medicine. AMP focuses on identifying and validating biological targets for diseases using genomic, proteomic, and other molecular data, accelerating the development of personalized treatments.

## **Importance of partnerships with multiple stakeholders**

Diverse partnerships across academic institutions, hospitals, patient advocacy groups, and registries are vital for streamlining precision patient finding and drug development. Such collaborations ensure that relevant patients can be identified at every point of entry based on their genetic and molecular profiles.

Partnerships with non-medical entities like faith-based organizations, public health departments, and housing agencies have been particularly effective in increasing patient engagement efforts in precision medicine.<sup>34</sup> These collaborations emphasize the importance of cross-sector partnerships to maximize reach and build meaningful relationships with participants, thereby enhancing the collection of genetic data essential for precision medicine initiatives.



# Future trends and innovations in precision patient finding

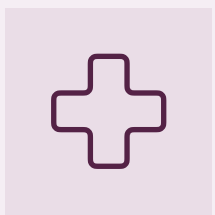
As technologies evolve and volumes of digital health data ever increase, there are a number of emerging trends developing within the precision patient finding landscape as trials move towards a more decentralized approach.



## Real-world data integration

Integration of real-world data such as EHRs and genomic data into the clinical trial process is becoming more prevalent and has been identified as improving recruitment efficiency, screening, data collection, and trial design.<sup>35</sup> As these trends continue to grow, emerging challenges and considerations will include: how to address patient anonymity and de-identification when working with such varied and comprehensive data from multiple sources, as well as questions surrounding data quality, consistency, and interoperability.

The possibilities of real-world data integration also have the potential to significantly influence clinical trial design, opening up the opportunity to utilize virtual and hybrid approaches which reduce burden on patients.



## Telemedicine

The emergence of telemedicine, such as video or telephone consultations and the use of wearable devices to gather data, is allowing healthcare providers to overcome geographical boundaries and bring consultations and clinical trials into patients' homes. As well as bringing healthcare and research opportunities to geographically remote communities, being able to engage patients from home has the potential to reduce barriers to trial enrollment, helping researchers establish if an individual is the right fit for a study without the need for them to travel. This reduces the emotional and physical burden on patients and reduces trial costs, such as travel expenses. Additionally, telemedicine enables researchers to screen a greater number of individuals at increased pace, contributing to a reduced trial timeline.

Importantly, digital data sharing and online consultations also enable from-home delivery of key services throughout the clinical trial process. For example, when genetic testing is part of the screening process, telemedicine enables the online delivery of genetic counseling sessions to empower patients to understand the potential outcomes of genetic testing and what their results mean for them.<sup>36</sup>

As new technologies and digital tools continue to evolve and become increasingly dynamic and sophisticated, so will their power to improve and accelerate patient finding initiatives.



## Patient-centric recruitment approaches

A growing focus on patient-centric approaches is also challenging “traditional” recruitment techniques.<sup>37</sup> By involving patients in trial design, integrating telemedicine approaches which reduce burden and barriers to participation, and by gathering insights directly from patient advocacy communities, trials are better able to address the unique challenges and concerns of specific patient communities. To date, research shows that designing trials with patients' needs, preferences, and experiences at the forefront leads to improved participant satisfaction, reduced recruitment timelines and an overall greater chance of success.<sup>38</sup>

Patient-centric approaches include trials designed with patient convenience in mind, such as minimizing travel requirements and simplifying procedures as much as possible without compromising data quality or patient safety. Ongoing patient engagement and clear, effective communication have also been highlighted as key aspects of a patient-centric approach.<sup>39</sup>



## Looking to the future

As precision patient finding approaches continue to develop, near future clinical trials are likely to be designed with an increasingly patient-centric and community-outreach focused approach.<sup>7</sup> Increased use of digital technologies and AI and ML analysis will enable leveraging of growing volumes of genomic and digital health data to deliver precision medicine approaches, accelerate recruitment, and reduce trial timelines and dropout rates. An overarching focus on greater transparency and enhanced communication, particularly around data use and security, is likely to emerge as patient awareness around data integration and its impact increases.



## Conclusion

Overall, effective implementation of precision patient finding programs has the power to accelerate clinical trial timelines, reduce costs, and mitigate risks including drop-out rates and trial termination. Harnessing tools such as genomic and health data integration, AI analysis, and e-consent, and coupling them with strong relationships with advocacy groups, patient registries and public-private partnerships provides a new patient-centric model for patient identification and recruitment. This not only improves cost and efficiency within trials, but enhances patient awareness and outlook and ultimately serves to deliver vital new therapies to patients, faster.



**Struggling with patient finding for your precision medicine research? Let's talk.**

Find out how Sano can support your team:

 [sanogenetics.com](https://sanogenetics.com)

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