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Driving Diversity, Equity, and Inclusion in Clinical Trials

EXPERIENCE-BASED GUIDANCE FOR SPONSORS

Health equity is essential and achievable

While the barriers and challenges are complex and exist across the health & life sciences ecosystem, sponsors of clinical trials are in a unique position to lead the change.

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There is a strong case for change

- U.S. population demographics are rapidly changing
- Drug treatment responses may vary across racial and ethnic groups
- Public Opinion Demands Accountability for diversity, equity, and inclusion (DEI)

Nearly **40%** of the U.S. population now identifies as non-white
[Brookings Institute]

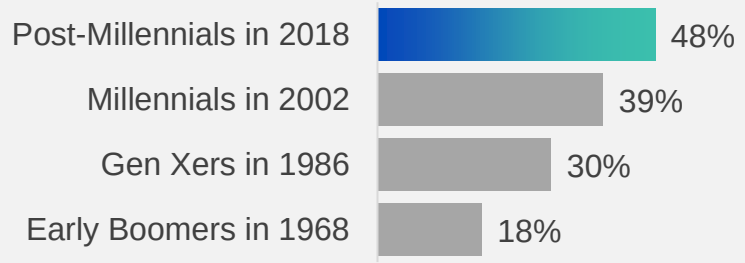
Almost **half** of post-Millennials are racial or ethnic minorities
[Pew Research]

Census data projects the U.S. will become majority non-white by

2045

[Brookings Institute]

Percentage of 6- to 21-year-olds who are non-white



[Brookings Institute]

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[Brookings Institute]- Frey, William H. "The Nation Is Diversifying Even Faster than Predicted, According to New Census Data." Brookings, Brookings, 9 Mar. 2022, https://www.brookings.edu/research/new-census-data-shows-the-nation-is-diversifying-even-faster-than-predicted/.
[Pew Research]- "Nearly Half of Post-Millennials Are Racial or Ethnic Minorities." Pew Research Center's Social & Demographic Trends Project, Pew Research Center, 13 Nov. 2018, https://www.pewresearch.org/social-trends/2018/11/15/early-benchmarks-show-post-millennials-on-track-to-be-most-diverse-best-educated-generation-yet/psdt-11-15-18_postmillennials-00-00/.

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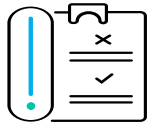
Understanding Current Challenges

Diversity, Equity, and Inclusion in Clinical Trials

Underrepresented patients face participation barriers at all stages of a clinical trial



Study Design

- Strict inclusion & exclusion criterion in study protocols

Recruitment

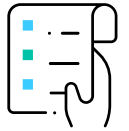
- Absence of cultural awareness in recruitment
- Lack of diversity among investigators
- Language barriers

Enrollment

- Lack of knowledge on how to enroll in a study

Participation

- Lack of transportation
- Work-related conflicts
- Unmet childcare needs
- Discomfort using medical technologies



Study Follow-up

- Inaccessibility of research findings

- Lack of health insurance or access to prerequisite treatments

- Misinformation about clinical trials
- Negative perceptions of clinical research due to past injustices
- Fear of mistreatment or exploitation

- Lack of technical literacy or internet access
- Anxieties about data privacy

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Provider bias can present additional hurdles to trial participation

Hurdle 1:

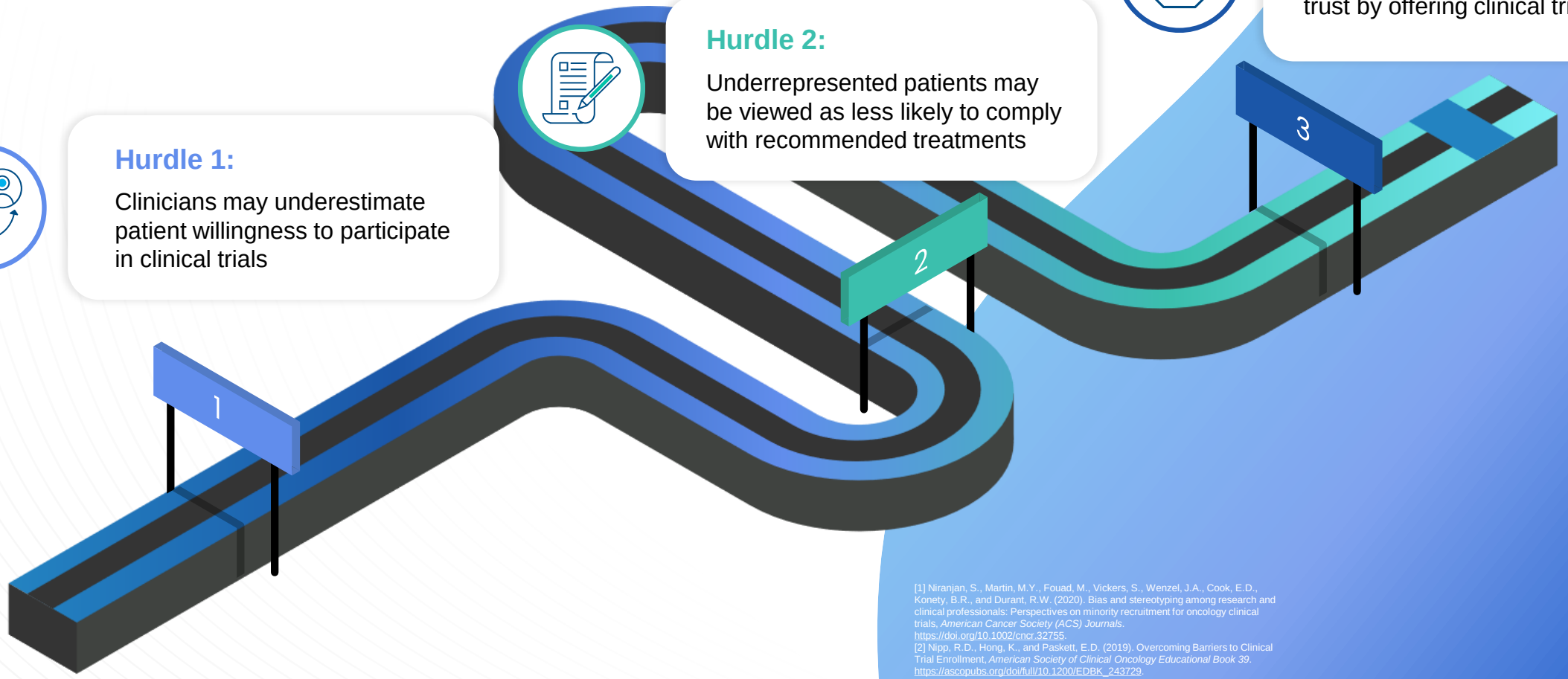
Clinicians may underestimate patient willingness to participate in clinical trials

Hurdle 2:

Underrepresented patients may be viewed as less likely to comply with recommended treatments

Hurdle 3:

Clinicians may fear loss of patient trust by offering clinical trials



[1] Niranjan, S., Martin, M.Y., Fouad, M., Vickers, S., Wenzel, J.A., Cook, E.D., Konety, B.R., and Durant, R.W. (2020). Bias and stereotyping among research and clinical professionals: Perspectives on minority recruitment for oncology clinical trials, *American Cancer Society (ACS) Journals*. https://doi.org/10.1002/cncr.32755.
[2] Nipp, R.D., Hong, K., and Paskett, E.D. (2019). Overcoming Barriers to Clinical Trial Enrollment, *American Society of Clinical Oncology Educational Book 39*. https://ascopubs.org/doi/full/10.1200/EDBK_243729.
[3] Hamel, L.M., Penner, L.A., Albrecht, T.L., Heath, E., Gwede, C.K., and Eggly, S. (2016). Barriers to Clinical Trial Enrollment in Racial and Ethnic Minority Patients with Cancer, *Cancer Control*, Vol. 23, No. 4. https://journals.sagepub.com/doi/pdf/10.1177/107327481602300404.

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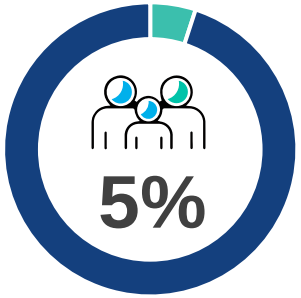
Oncology trials introduce increased complexity

Considerations in Oncology

- Use of advanced precision medicine leads to more **complicated trial design,** including molecular profiling
- Cancer can be life threatening and new therapies may be intended to help **improve a patient's quality of life rather than cure the disease**
- Placebos are rarely used, and sponsors must demonstrate **safety and efficacy compared to the existing standard of care (SOC)**
- Existing cancer treatments can be very physically demanding, with **extreme side effects** such as physical pain, hair loss, nausea and vomiting
- Oncology trials **are lengthy to complete** and treatments **may not show immediate or intended benefits**

Impacts on Trial Recruitment and Retention

- There may be **strict trial exclusion criteria and fewer sites** able to meet more complicated requirements
- Patients **may not see the benefit** of study participation or may **opt out of treatment all-together**
- Patients may experience **fear or anxiety about new treatments**
- Trials may encounter **patient retention challenges**



Only **5% of eligible adult cancer patients** are estimated to participate in clinical trials [FDA]

These challenges may be compounded for patients from underrepresented backgrounds

[1] Ibrahim, MD, A. Alternatives to Using Placebos in Cancer Clinical Trials, FDA. 2019. https://www.fda.gov/media/138004/download
[2] Fountzilas, E., Tsimberidou, A.M., Vo, H.H. *et al.* Clinical trial design in the era of precision medicine. *Genome Med* 14, 101 (2022). https://doi.org/10.1186/s13073-022-01102-1

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Addressing Disparities

Diversity, Equity, and Inclusion in Clinical Trials

Sponsors employ several strategies to expand clinical trial representation

Corporate Grants

Committing funds and/or expertise and coaching to outside organizations working to increase diversity, equity, and inclusion in clinical R&D

Leveraging Data

Using data to measure current state trial diversity performance, build in targeted improvements, and achieve greater transparency of outcomes

Policy Advocacy

Educating policymakers to impact legislation and/or health authority guidance in support of increased trial diversity

Patient Education

Spreading awareness and resources to help overcome patient information gaps, misconceptions, and resistance to clinical trial participation

Partnering with CROs

Collaborating with sites and investigators to diversify recruitment and/or providing education to develop investigators from underrepresented groups

Site Selection

Prioritizing collaboration with CROs located in diverse communities or where there are already strong diversity recruitment outcomes

Study Design

Designing studies and protocols to support diverse patient enrollment

Removing Patient Barriers

Allocating support, such as transport or childcare assistance, to enable trial participation

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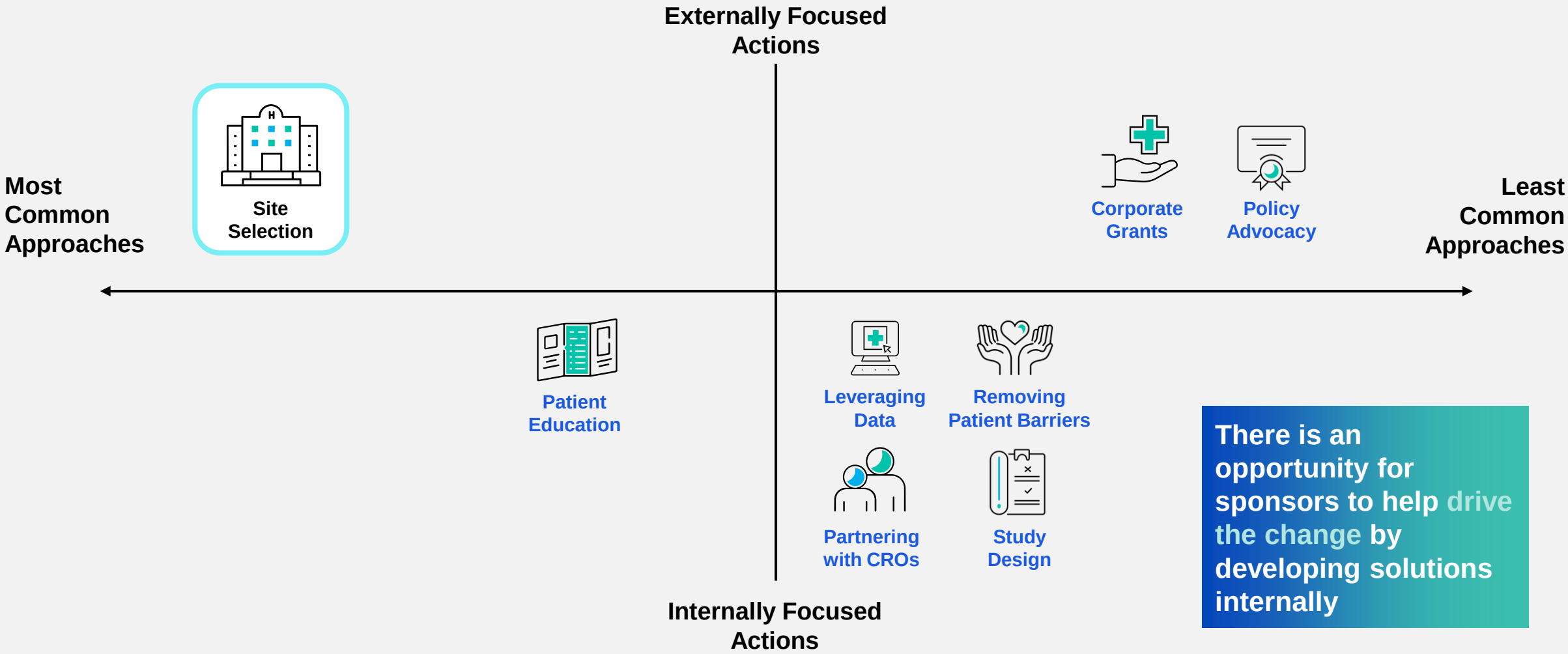
Many sponsors focus heavily on site selection, placing the greatest burden on investigators



There is an opportunity for sponsors to help drive the change by developing solutions internally

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Acquis partners with sponsors to help close existing gaps in clinical trial enrollment

Reinforcing Drug Safety

Proactively manage and study the potential for differing drug treatment responses across patient groups, based on their unique physiological and social determinants of health (SDOHs)

How Acquis Can Help:

- Inclusive program and study design
- Partnership with clinical to anticipate treatment responses by group

Building Patient Trust

Engage directly with underrepresented patients, who may be skeptical due to the painful historical legacy of mistreatment by researchers, fearful of emerging medical technologies, or critical of the pharmaceutical industry

How Acquis Can Help:

- Patient experience design and journey mapping
- Patient outreach & communications strategy
- Diverse recruitment training strategy

Actioning Guidance

Set the stage for success in the drug approval process by implementing FDA and global health authority recommended approaches to increase trial representation

How Acquis Can Help:

- Race & Ethnicity Diversity Plan development, execution, and measurement (per FDA guidance)
- Regulatory compliance assurance
- Best practice adoption

Leveraging Diversity Data

Acquis supports the development and implementation of a **diversity data strategy** to improve outcomes measurement and response across all facets of clinical research. We can also support the creation of **data-informed industry thought leadership** to help strengthen market presence

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We support clients along an end-to-end continuum

Current State Maturity Assessment

- **Evaluate historical trial data** across therapeutic areas
- **Review early stage R&D assets** to identify priority focus areas for further discovery

Trial Diversity Strategy & Roadmap Development

- **Build the business case** and develop an enterprise-wide strategy for trial diversity
- **Launch a Diversity in Clinical Trials program** within early stage companies

Clinical Trial End-to-End Program Management

- **Leverage diversity SME knowledge** combined with deep clinical trial program management experience
- **Build industry best practices and patient feedback** into clinical trial operations

Stakeholder Buy-in and Change Management

- **Develop a change management strategy** to embed diversity as a core value in clinical research
- **Deploy advanced communication, training, and evaluation** tools

Continuous Improvement & Best Practice Adoption

- **Design quality governance processes** to ensure performance against diversity KPIs & standards ahead of trial submission
- **Turn health authority guidance** into real-world best practices

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Clinical Development Strategy

Partnered with head of clinical development and chief medical officer on clinical trial development strategy

Business Challenge

- An early-stage gene therapy company initiating execution of its clinical development strategy experienced churn in decision-making and difficulties meeting early regulatory and clinical milestones

Our Approach

- Assessed current gaps within the clinical roadmap to ensure alignment to corporate goals
- Identified stakeholders needed for inputs to clinical development strategy and documents. Created pitch deck to recruit partners and key opinion leaders (KOLs) into program, and conducted a literature review to identify the right experts to engage. Implemented a KOL CRM to streamline interactions, and identified patient advocacy groups and forums to gain an understanding of the patient population and inclusion criteria
- Gathered competitive intelligence as an input to study design and regulatory strategy. Developed a clinical development plan and protocol for the company's primary indication, and partnered to develop a mobile application to capture patient reported outcomes. Collaborated with branding agencies to establish compelling patient retention campaigns

Results and Value

Established a decision-making framework to formalize clinical design and key study documents across clinical, medical, regulatory, and the patient community

Operationalized the medical function by standing up processes and tools that gave leadership near-time visibility on clinical activities

Created an advisory network inclusive of key opinion leaders, patient advocacy, and regulatory consultants to provide input into protocol and clinical roadmap

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Trial Planning and Clinical Operations

Developing and operationalizing multiple studies at an early-stage biopharmaceutical

Business Challenge

- A lean, early-stage pharmaceutical CMO needed support to plan and operationalize multiple studies for two molecular assets in unrelated disease areas

Our Approach

- Workshopped ideal and base-case program roadmaps with internal stakeholders. Designed trial scenarios, and facilitated cross-functional collaboration to align on trial designs
- Created the vendor selection criteria and coordinated CRO evaluation and selection, including bid defense meetings. Oversaw trial enrollment and start-up activities, including drug production, packaging and labeling
- Represented the “voice of clinical” at regular data review meetings. Resolved and escalated issues across functions and with CROs. Supported monitoring of safety protocols, site issues, and data reporting, and created a dashboard for visibility into clinical operations
- Ensured regulatory compliance/submission readiness through best practices for maintaining a proper audit trail

Results and Value

- Drove alignment across key functions and stakeholder groups on trial designs to enable the most efficient and cost effective path forward for asset development
- Facilitated the CRO evaluation and selection process, including bid defense meetings
- Led risk identification and escalation, budget management, external vendor oversight and direction (e.g. CRO) to drive on-time trial completion

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DEI in Strategy & Governance

Aligning decision makers at a global pharmaceutical company around a shared DEI vision & execution strategy

Business Challenge

- A global pharmaceutical company desired a revamp of its Diversity, Equity, and Inclusion strategy and support

Our Approach

- Conducted an evaluation of the organization's past diversity, equity, and inclusion (DEI) initiatives. Reviewed approaches that had previously been explored and/or implemented, and helped to uncover the factors behind DEI program successes and failures
- Facilitated a series of leadership workshops to identify and prioritize the top DEI initiatives
- Defined a DEI roadmap, governance framework, and associated accountability structures, to unify independent DEI activities across multiple sub-sectors. Enabled for enterprise-level management, tracking and measurement of DEI outcomes
- Delivered recommendations on defined DEI programs and initiatives, including organizational training & development and the launch of new partnerships and recruitment efforts within historically Black Colleges and Universities (HBCUs)

Results and Value

- Realized the organizational vision of establishing a formal DEI governance and reporting structure
- Defined priority initiatives for the organization and sub-sectors, and helped to successfully implement several of the flagship initiatives identified
- Adopted best practices tailored for the Compliance organization's unique business needs and the long-term sustainability of the DEI program

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Our people make the difference

Acquis **embraces all differences** and is committed to learning, equity, and community engagement. These DEI commitments are reflected in how our team partners with clients.

[Learn more here]

#1 Ranked #1 among the **Top 5 Consulting Firms that Support Women Leaders** [1]

Featured among **4 Companies Committed to Diversity & Inclusion**[2]

By Ivy Exec

[1] Ivy Exec, [2] Ivy Exec

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Meet our Clinical Trial Diversification Team

Meghan Marx

Lead, Health Equity

Meghan is passionate about public health. She has stood up, managed, and operationalized a wide range of programs and projects to increase the efficiency of healthcare delivery systems while also ensuring equitable access to patient care and increased representation in clinical research & development

Vivian Lee

Clinical Research Expert

Vivian is an explorer at heart. She follows her curiosity to discover creative solutions, pioneer paths to sustained results, and guide her clients to an innovative future. Her approach to designing a robust clinical trial is to embed the perspectives of all the stakeholders involved – patients, providers, payors and beyond

Vanessa White

Health Equity Expert

Vanessa's personal and professional journey is driven by the desire to bring better care to communities where it's needed most. She is channeling her talents to drive equitable impacts to historically underrepresented communities through authentic strategies and techniques

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Advance DEI in your clinical trials

Contact us for an exploratory discussion:
acquis@acquisconsulting.com

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