A Guide for Doctors to Clinical Research

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SIKHS In Clinical Research

Diversity. Equity. Inclusion.

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Sikhs in Clinical Research (SICR)

SICR is committed to playing its part in improving access to clinical trial opportunities for both the patients and the clinical research workforce with the goal of reducing disparities and enhancing healthcare equity.

Why is Diversity important?

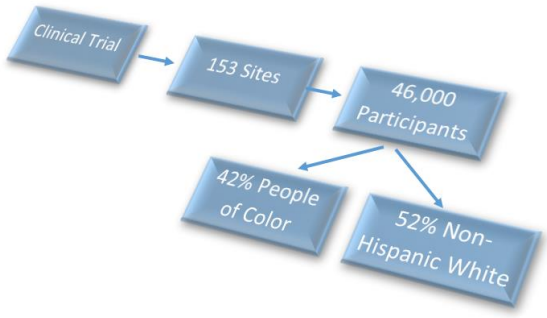
Acknowledging, emphasizing, and recognizing diversity and inclusivity among diverse communities is vital to successful new drug development processes. Including diverse patient pools to clinical trials brings new approaches and the potential for more effective treatments with generalized results[1]. Clinical research needs to represent diverse researchers and patient populations as it is imperative to collect diverse data which in turn leads to innovative treatments for all[2].

Improving the diversity of clinical trial participation is one of the most important initiatives across the life sciences industry and sponsor companies in the world are now using new insights to create strategies that improve diversity, access, and equity across their trials[1].

A Study Example

As an example, to increase diversity in a trial, a sponsor biopharma company reached out to 153 local clinical trial sites across the U.S., Argentina, Brazil, South Africa, Turkey, and Germany. These local sites were able to enroll more than 46,000 participants, and approximately 42% were Asian, Black, Hispanic/Latinx, or Indigenous/Native American, with 58% being non-Hispanic White [3, 4].

Though these numbers don't fully represent the global population, the diversity percentages are higher than in most clinical trials, providing evidence that public awareness and a network of community sites could be effective to recruit more diverse populations in clinical trials[3, 4].



Participants	Overall Study	U.S. Only
Asian	5%	6%
Black	10%	10%
Hispanic/Latinx	26%	13%
Native American	1.0%	1.3%

Sites and sponsors struggled with clinical trial diversity long before the COVID-19 pandemic began. Roughly 20% of new drugs have different effects depending on a person's race[4]. This makes it vital for new treatments to be tested on a diverse patient population.

However, many underrepresented patients don't have access to clinical trials. 70% of the U.S. population lives more than 2 hours away from an academic medical center[5]. This makes it difficult for elderly people, people with disabilities, and people who work hourly jobs to join trials[5].

Doctors

SICR is working to bring awareness to increase the involvement of doctors as investigators in clinical research. This has a long-term impact and brings research to the door of diverse patients, in their local setting, with doctors they already know, overcoming two of the key barriers to diversity and inclusion and making a positive difference. When doctors from diverse communities expand their skills into clinical research, they expand access to medical care for their patients with innovative treatment options[2].

Every stakeholder including the doctors must make sure to work on reaching poorly engaged communities and take actions to overcome the demographics logistic barriers, and previous misconceptions about trials making patients uncomfortable and build a trustworthy relationship with patients[2,6].

Current Challenges

Sikh immigrants in U.S health care settings have been reported to feel nervous in front of other doctors and like to shy away from many direct encounters usually because of communication issues and expressing their feelings. The cultural distance between a doctor and a patient reduces trust and empathy, compromising the quality of care provided. It is recommended to the management committee of Sikh Gurudwaras to print and keep educational brochures in Sikh Gurudwaras, which talk about easy steps to understand the healthcare system of America. For Sikh community members, it is hard to understand how the healthcare system works in America and they are still in a process of learning it[7].

SICR has also reported a lack of awareness among the Sikh community about clinical research from the perspective of both the workforce and patient participation based on the data collected through webinars, routine queries, and surveys during community events arranged by SICR. Healthcare professionals from a Sikh background such as Medical Assistants, Nurses, Foreign Medical Graduates, and Pharmacists during the surveys have reported no knowledge of Clinical Research careers probably because no one ever told them before and/or they never heard about it before. Resident physicians, Fellows, and Attending Physicians want to learn

clinical research but struggle to find out the best resources and the right path to get into clinical research to add to their experience. Doctors, if they have an independent practice, do not want to add extra responsibilities and tasks to their routine work and if they work as an employee their workplaces do not run clinical trials so they can opt-in.

How to overcome recruitment barriers?

The importance, and challenges, of enrolling diverse patient groups into clinical trials are well known without notable success and evidence of increased diverse trial participation[8] because of a wide variety of barriers including logistical barriers, cultural/language differences, and lack of resources to name a few[1,2]. One investment could be to focus on engagement at a community level to overcome historical precedents and improve levels of trust in clinical research. Decentralized trials enable more patient flexibility and less reliance on clinical trial sites thereby reducing the need for travel and/or time off work, removing potential conflicts with an individual's life and responsibilities, which can also be key barriers to enrollment of diverse populations[2,5].

The patient must be at the heart of all considerations. By the time an individual living with a cancer diagnosis, for example, is discussing the possibility of a clinical trial, they will have a strong relationship with an oncologist and their team, and if they are already under the care of a specialist or academic center that is active in clinical trials, making it easy for them to consider trial options. However, if taking part in clinical research meant traveling to a different medical office, with time and travel implications, and facing the prospect of a different clinical setting and a new relationship with a new doctor, this could impact the willingness to consider clinical research. Supporting research in the setting where the patient is already receiving care enables diversity in patient enrollment as well as diversity in the workforce with investigators coming on board from diverse communities.

Our responsibilities

We need to assess earlier within the patient journey where the gaps are. We have a responsibility to listen and communicate transparently with patients. To minimize challenges for the patient, SICR takes the approach of empowering doctors supporting research in the setting where the patient is receiving their care, and that is most familiar to them. This is a core part of its strategy to enable diversity in patient enrollment.

Factors such as socioeconomics, education, degree of acculturation, and English proficiency have an enormous impact on an individual's health beliefs and behaviors. All these factors challenge one's ability to understand and be treated as a patient in cross-cultural settings.

What we need to work towards

SICR anticipates that when the community will come into leadership roles as Clinical Research Coordinators, Research Nurses, Principal Investigators, and Sub- Investigators, it eventually will improve clinical trials participation as advancing diversity in clinical trials requires a cultural mindset as well as enhance diversity in the clinical research workforce. We have a responsibility to long-term investments to benefit our community, including health literacy education, and broad education for people to understand how to explore clinical trials as a healthcare option to build foundations of health equity[9].

Clinical research could be a great treatment option for an individual for whom other treatment options do not work especially in the case of individuals diagnosed with rare diseases, when everything else has been tried with no success, clinical research could bring hope. However, if the doctors are not into research, patients may never find out alternative options. On the other hand, research-active doctors can educate patients on clinical research to explore alternative treatment options.

Community Building

SICR is working towards promoting workforce diversity and awareness to enrich the community and their work with innovation.

Sikh core values of **trust, integrity, ethics, humility, compassion, equality, and justice** become operative in the Sikh way of life and the work we do every day. Clinical research is an opportunity to be part of a larger transformation and contribute to advancing science and medicine.

Community building is important to innovate faster, find better solutions to problems, attain higher productivity, and help reach our goals quickly. Through the SICR professional networking group, the community can come together to share, connect, and exchange ideas and value-driven experiences. SICR is a great opportunity to create a space for knowledge sharing and the act of sharing is a very empowering practice that can turn into a great supporting source to help everyone grow.

When communities come together, they become stronger and more visible. Every community has the potential to grow and excel and set an example for future generations.

Benefits of becoming a Research Investigator

Clinical Research has always been an interest of many doctors, but with the day-to-day clinic operations, they get too busy and are not able to give attention to a new venture. However, it is a great opportunity to enhance patient care all the while leveraging their existing resources and infrastructure[10].

Clinical Research workflow in a Practice

Clinical trials are a great opportunity for doctors to learn new skills, explore new challenges, and contribute to the advancement of medicine and science as well as the opportunity to earn additional revenue. We have listed the following steps to help you understand and walk you through the typical workflow[11].

1. The first and foremost step would be to complete some mandatory training to acquaint you with the basic principles and processes involved in conducting research on human subjects. The staff who will be involved in seeing research patients during visits or other research activities would also need to be trained or a CRC (Clinical Research Coordinator) can be hired.

2. Clinical research can be conducted in private practices, group practices, clinics, or hospital settings. Existing infrastructure, equipment, and resources can be leveraged to have the research program up and running. There may be a need for some additional

equipment in order to comply with the regulatory requirements such as monitoring devices to record the temperature of investigational products or the CLIA waiver for the lab; which can be arranged and worked on with some additional guidance.

3. Once the staff is trained and the site is research-ready, it is time to find the appropriate trials that match the interest and specialty of the practice. Physicians who are research naïve can start with observation trials, sample collection studies, and phase 4 trials to help gain insights into clinical trials as well as experience working with different stakeholders such as Sponsors (Pharmaceutical or medical device companies), CROs (Clinical Research Organizations), IRB (Institution Review Board), Lab vendors, etc. in a regulated environment.

4. In the next steps, the Sponsor/CRO would evaluate the site to make sure it is equipped and has the specific patient population they are looking to recruit. The Sponsor/CRO will also make sure that the physician's medical license is active in the state and that the training of research staff is up to date. If the site is selected both parties will sign a contract and the Physician agrees to take the overall responsibility of conducting a trial at his/her site. The startup process also includes approval from the IRB (Institution Review Board) before any study activities start at the site to protect the rights, safety, and well-being of study participants.

5. Following the IRB approval and the contract/budget with the Sponsor/CRO is finalized, a site initiation visit (SIV) is scheduled by a CRA (Clinical Research Associate) usually hired by the Sponsor/CRO to ensure that everything is in place for the site to begin enrolling patients and protocol training to the staff is provided. The CRA would stay in touch with the site throughout the study and visit the site from time to time to assure the integrity and accuracy of the research data being collected at the site.

Empowerment

This initial guide is to empower Doctors to come forward to be a part of this research industry. We as a Sikh community have excelled in almost every healthcare profession, clinical research should be no exception. SICR provides a nurturing and supportive environment to cultivate the next generation of diverse leaders in clinical research and invites you to be a part of its professional network.

Further resources will become available for the Sikh community.

Authors

Author: Ekta Grewal, in Punjabi: ਏਕਤਾ ਕੌਰ

Ekta Grewal is the Founder and CEO of 'New Life Clinical Research, LLC (NLCR) and 'Sikhs in Clinical Research' (SICR). She started her career as a researcher at world-renowned universities, Bournemouth University in the UK and the University of Arizona in the U.S. working in collaboration with a stellar team of doctors, research scientists, and bioengineers. She has significantly contributed to writing articles, reports, NIH grants, and manuscripts at the university level. She later pursued her career as a lead coordinator, development specialist, and research manager at multiple sites in the U.S. working in collaboration with world-renowned sponsors/CROs. Over the years she has worked in different capacities, including building study pipelines for the sites, boosting patient enrollment through refined strategies, and managing day-to-day operations of clinical trials. Her significant exposure to different aspects of clinical trials, including supporting physicians to build research arms in their practice, training research coordinators along with related regulatory functions, data management, audits, providing oversight for cancer trials (NCI/Pharma) in community hospitals for quality assurance and compliance, cross-functional research knowledge, and execution successes, equipped her with the creative abilities to grow and led to the formation of NLCR and SICR. She is very passionate about research. Her goal with SICR is to play her part in improving access to clinical trial opportunities for both the patients and the workforce with a focus on reducing disparities and enhancing equity among diverse communities.

Guest Author: Amanjot Kaur Khera, in Punjabi: ਅਮਨਜੋਤ ਕੌਰ

Aman Khera, a global regulatory affairs leader and strategist has over 26 years' experience in the clinical research industry. She is a recognized expert, providing global strategic direction in regulatory affairs. She has led a wide variety of regulatory projects providing regulatory strategy and development services in many therapeutic indications. She is passionate about helping client sponsors develop comprehensive regulatory strategies and has worked with a number of agencies across the world. She is well respected and recognized for her track record in anticipating and addressing inevitable regulatory challenges in the development journey, often sought out in industry and beyond for her insights in clinical research. Her insights has changed the way people think about regulatory affairs and has resulted in fewer late-stage

surprises, smoother trials, and optimal outcomes for the development of new therapies. She is committed to diversity and inclusion in clinical research and advises the industry on creating actionable, yet practical strategies. She holds the position of Vice President, Global Head of Regulatory Strategy at Worldwide Clinical Trials. She serves on the emTRUTH advisory board, bringing a unique perspective on how regulations, ethics, and compliance interplay within blockchain for healthcare. She is also a 2021 PharmaVOICE 100 honoree, recognized as one of the most influential and inspiring people in the life sciences industry. She volunteers her time with organizations such as DIA, The Organization for Professionals in Regulatory Affairs (TOPRA) and the Regulatory Affairs Professionals Society (RAPS) as well as an Advisor to Sikhs in Clinical Research and Guest Speaker to New Life Clinical Research for Clinical Research Training Program.

Guest Author: Amrit Anand, in Punjabi: ਅੰਮ੍ਰਿਤ ਅਨੰਦ

Dr. Anand is a specialist in autoimmune conditions who completed his undergraduate work in Chemistry at the University of Iowa and in Physical Therapy at the University of Oklahoma. During his time at these academic centers, he was involved in various research projects and completed his honors research in Inorganic Chemistry. Following his undergraduate studies, he practiced as a licensed physical therapist for four years in the Chicago area where he also was involved in studies for collecting patient data and contributed to some publications. His desire to help others led him to grow further and he enrolled in a medical school where he earned his medical degree in 2004. He completed a residency program in Internal Medicine at Michigan State University affiliated program and Rheumatology fellowship training at the University of Iowa Hospitals and Clinics, Division of Allergy-Immunology and Rheumatology. En route, he was exposed to many research opportunities. Now, as a board-certified Rheumatologist, he is committed to helping patients living with arthritic disorders and autoimmune diseases. Besides he also serves as an investigator on various clinical research studies at his current workplace Ortho Illinois. Dr. Anand supports the mission of Sikhs in Clinical Research and will be volunteering his time at SICR to help bring awareness to the community about clinical research.

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