ClinWin Research Approach to Developing Clinical Research Workforce in Africa

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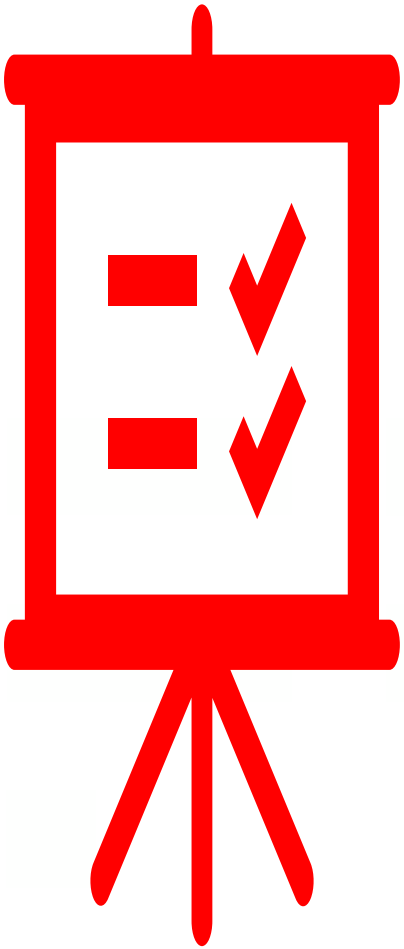
Director.

Outline



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- Our Approach Clinical Workforce Development
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- Clinical Research Training
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About us

- ClinWin is a mid-sized Contract Research Organization (**CRO**) based in Nairobi, Kenya, with regional offices at Kampala, Uganda and Kigali, Rwanda. With locally based Clinical trials Monitoring Consultants in Khartoum, Sudan; and Tanzania.
- Provides outsourced Clinical Development and Strategic Consulting Services
- We subscribe to One Health approach in our service offerings
- We have expertise in projects delivery and deployment of life saving health technologies and interventions in resource limited settings.
- Expertise in Early, Late-Phase and Real-World Evidence

Our Services

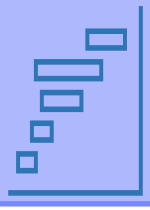
Feasibility and Study Start Up

- Feasibility and Site Identification.
- Ethical and Regulatory Approvals.
- Trial Site Capacity Development.

Clinical Monitoring and Management

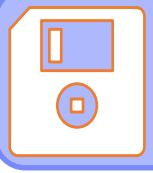
- Clinical Trials Monitoring.
- Clinical Quality Assurance Audits.
- Medical monitoring and Safety
- Investigational Product Management

Project Management



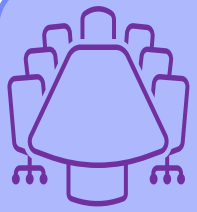
- Study Management.
- Quality Management.
- Team and Vendor Management.
- Project Administration.

Data Science and Technology



- Data Management and Analytics.
- Artificial Intelligence
- Technology Solutions

Strategic Consulting



- Clinical Research and CRA training.
- Clinical Study Documents Development.
- Regulatory affairs consulting
- Functional Services Provision
- Surveys and Operational Research

Global Clinical Trials Outlook, 2023

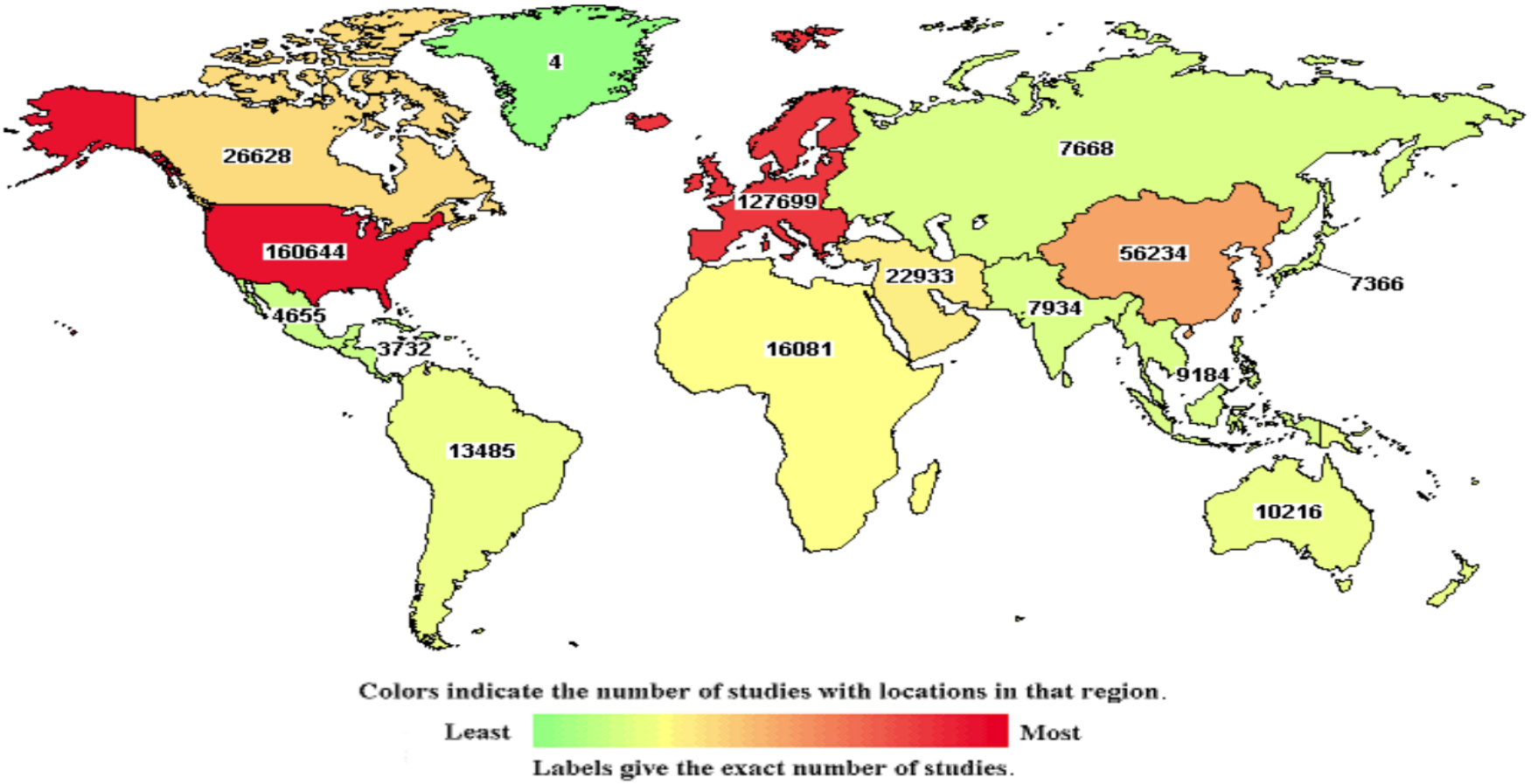
Year First Posted	Start of Year	During Year	End of Year
2000 †	1,255 †	2,119	2,119
2001	2,119	1,773	3,892
2002	3,892	1,378	5,270
2003	5,270	3,588	8,858
2004	8,858	3,166	12,024
2005	12,024	12,798	24,822
2006	24,822	10,917	35,739
2007	35,739	12,549	48,288
2008	48,288	17,564	65,852
2009	65,852	17,009	82,861
2010	82,861	17,345	100,206
2011	100,206	17,816	118,022
2012	118,022	19,463	137,485
2013	137,485	20,431	157,916
2014	157,916	23,310	181,226
2015	181,226	24,106	205,332
2016	205,332	27,787	233,119
2017	233,119	29,176	262,295
2018	262,295	30,952	293,247
2019	293,247	32,516	325,763
2020	325,763	36,724	362,487
2021	362,487	37,018	399,505
2022	399,505	38,035	437,540
2023	437,540	7,498 ‡	445,038 ‡

- The global clinical trials market size is expected to reach USD 68.9 billion by 2026[1]. *Compound Annual Growth Rate (CAGR) of 5.7% during the forecast period*.
- Key drivers include *globalization of clinical trials, development of new treatments such as personalized medicine, augmenting evolution in technology, and rising demand for CROs to conduct clinical trials.*
- Increase in investment in new product development in emerging countries.
- More services from drug discovery to post-marketing surveillance has further simplified the life for mid-size and small-scale pharmaceutical and biotechnological organizations by providing them the option to outsource what they think is beyond their core expertise.

1. https://www.reportlinker.com/p05763821/?utm_source=PRN

Number of Registered Global Studies by Year and Map

://www.clinicaltrials.gov/ct2/resources/trends#MapOfStudies

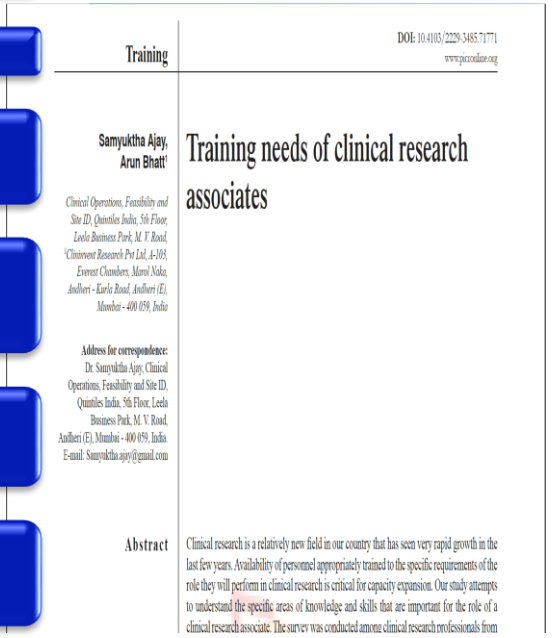


The demand for clinical trials is growing as the pool of clinical research associates (CRAs) and other trial workforce professionals is shrinking. https://acrpnet.org/is-the-clinical-trial-workforce-prepared-for-the-future/

The Rationale for Clinical Workforce Development

- Ethical, regulatory and ICH GCP compliance - *ICH GCP 2.8 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).*
- Global priority to develop clinical trials work force to meet increasing CR workload needs.
- Emerging infectious diseases and NCDs
- Emerging new technologies
- Increasing number of clinical trials conducted locally in Africa,
- Wellbeing and safety of research participants
- Need for qualified and competent workforce to conduct clinical research
- Public confidence in clinical research
- Lack of clear career paths and adequate workforce training is contributing to the shortage of skilled personnel.

Economist Report Issues Call to Action: Invest in Clinical Research Workforce
https://acrpnet.org/2018/07/10/economist-report-issues-call-to-action-invest-in-clinical-research-workforce/



Training

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www.picronline.org

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Training needs of clinical research associates

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Abstract

Clinical research is a relatively new field in our country that has seen very rapid growth in the last few years. Availability of personnel appropriately trained to the specific requirements of the role they will perform in clinical research is critical for capacity expansion. Our study attempts to understand the specific areas of knowledge and skills that are important for the role of a clinical research associate. The survey was conducted among clinical research professionals from

The Role of Clinical Research Organizations (CROs)

Definition - *Contract Research Organization (CRO) - A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. ICH GCP 1.20*

ICH GCP 5.2.1 A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.

Demand for clinical trial personnel has been increasing, with average compound annual growth in monthly job postings activity of 9.3 percent across all clinical research positions.

Africa is home to locally registered and international CROs.

Qualified and experienced team is critical to bring new products to market quicker.

The global clinical trials market size is expected to reach USD 68.9 billion by 20261

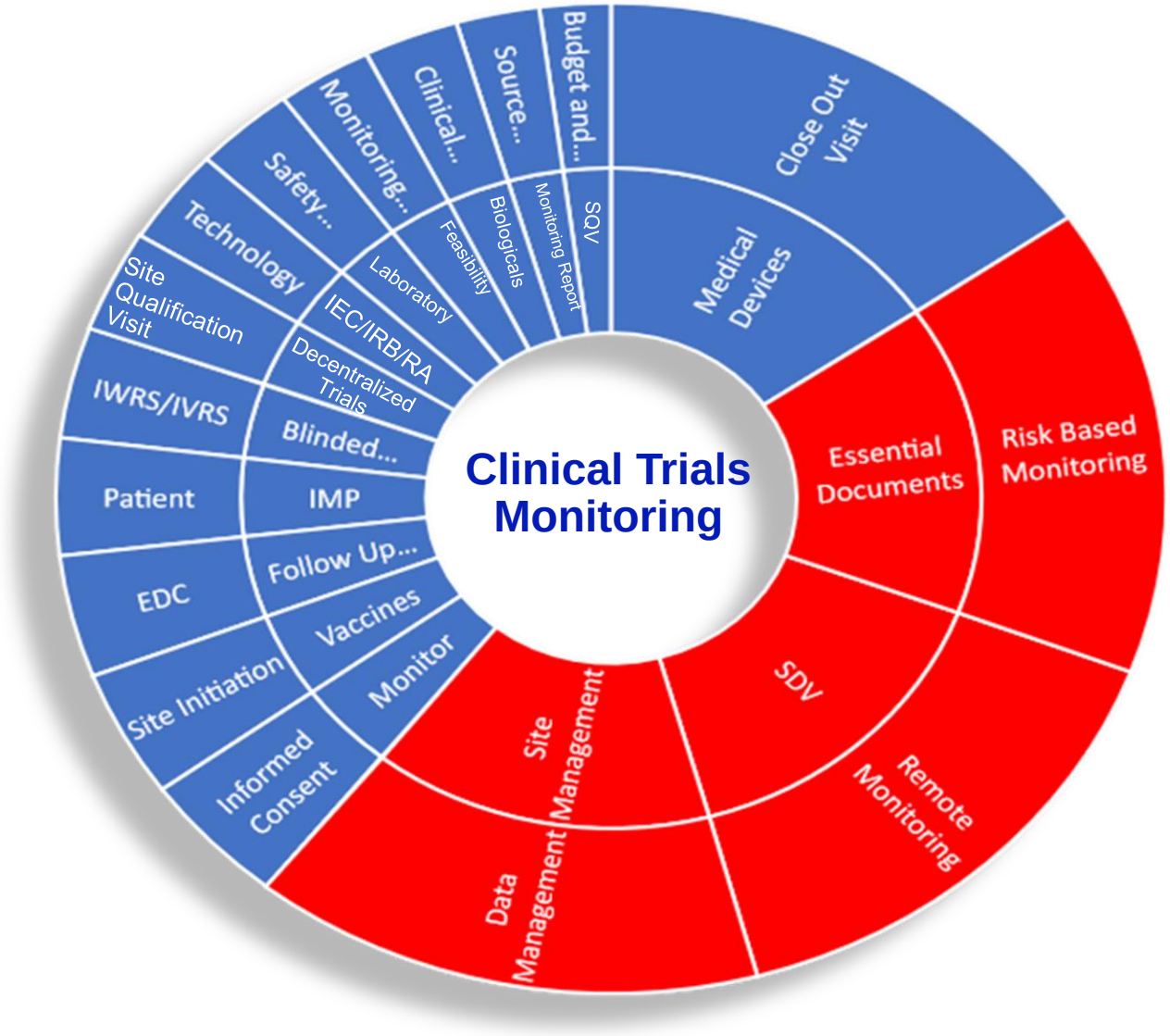
Clinical Research Training

ClinWin in partnership with KAVI Institute of Clinical Research, University of Nairobi conducts short courses in Clinical Research.

We offer skills-based and tailored courses in:

- Entry and Advanced Level Clinical Trials Monitoring
- Clinical Trials Coordination and Site Management
- Good Clinical Practice
- Data Management
- Bioethics
- Good Clinical Laboratory Practice
- Vaccinology

Clinical Trial Monitoring Course Outline



Our Approach to Clinical Research Workforce Capacity Development

ClinWin-KAVI ICR UON Clinical Trial Monitoring Training

- Candidates express interest - application +CV
- Admitted for the CRA Course
- Certificate of Completion offered by KAVI Institute of Clinical Research (KAVI ICR)– University of Nairobi & ClinWin Research Services

Clinical Monitoring Internship

- Candidate invited to apply for paid internship.
- Applicants are interviewed by panel comprised of senior Clinical research professional from other CROs and industry/Pharma,
- At least two candidates are selected, best on panelist scores.
- On-boarding, training and shadowed field monitoring practicum with senior ClinWin teams, for 3 months.

Fulltime CRA

- Performance evaluation conducted after 3 months.
- Those meeting and exceeding expectation on 360 degrees review are invited to join the CRA team on fulltime basis.
- Those not met expectations and or not interested to proceed with CRA role, the contracted is terminated and letter of support provided for future opportunities.

Qualified and Experienced CRA/Monitor

- Further training at Msc Clinical Trials/Research, PhD, CRP or SOCRA Certification.
- Membership of Professional Clinical Research Associations – ICR, ACRP, CRS Kenya, SACRA

Clinical Trials Monitoring Training

Sep 2017
Signed MOU Between University of Nairobi and ClinWin Research. To conduct collaborative research and training

October2019
Entry Level Clinical Monitoring training.

20 participants

November 2020
Entry Level Clinical Monitoring training.

15 participants

March 2022
Entry Level Clinical Monitoring training.

23 participants

KAVI ICR/UON – ClinWin Research Clinical Monitoring Course

May 2018
Advanced CRA Course for EACTRC conducted in Nairobi.

10 Participants

February 2019
Drugs for Neglected Diseases Initiative, Clinical Operations team Advanced Monitoring training .

8 participants

August 2019
Drugs for Neglected Diseases Initiative, Leishmaniasis Monitoring team training .

8 participants

August 2021
Entry Level Clinical Monitoring training.

17 participants

October 2022
Entry Level Clinical Monitoring training, UGANDA

13 participants

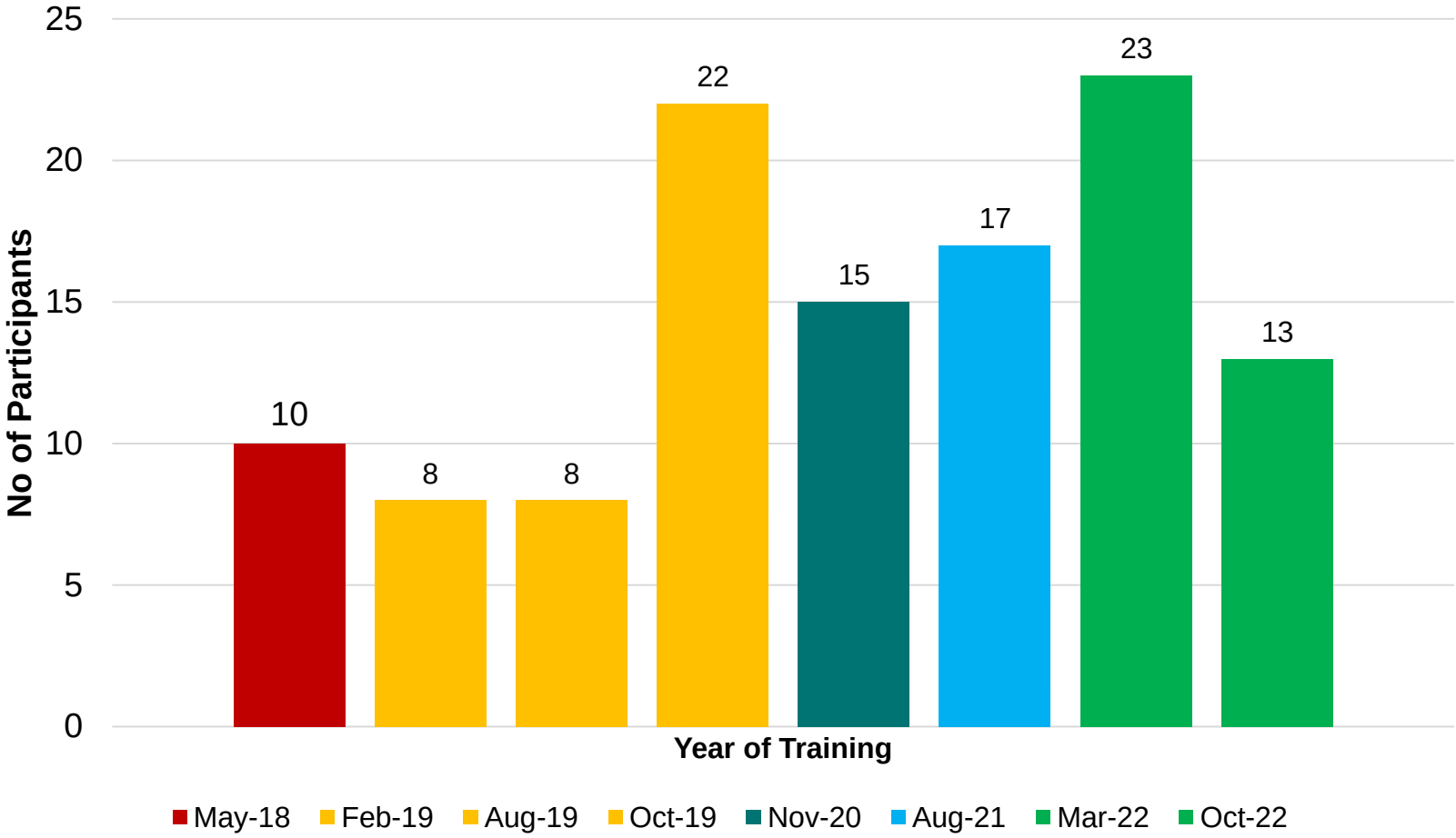
Our Approach to Clinical Trials Site Development

We conduct site assessments and design capacity development plan based on site needs.

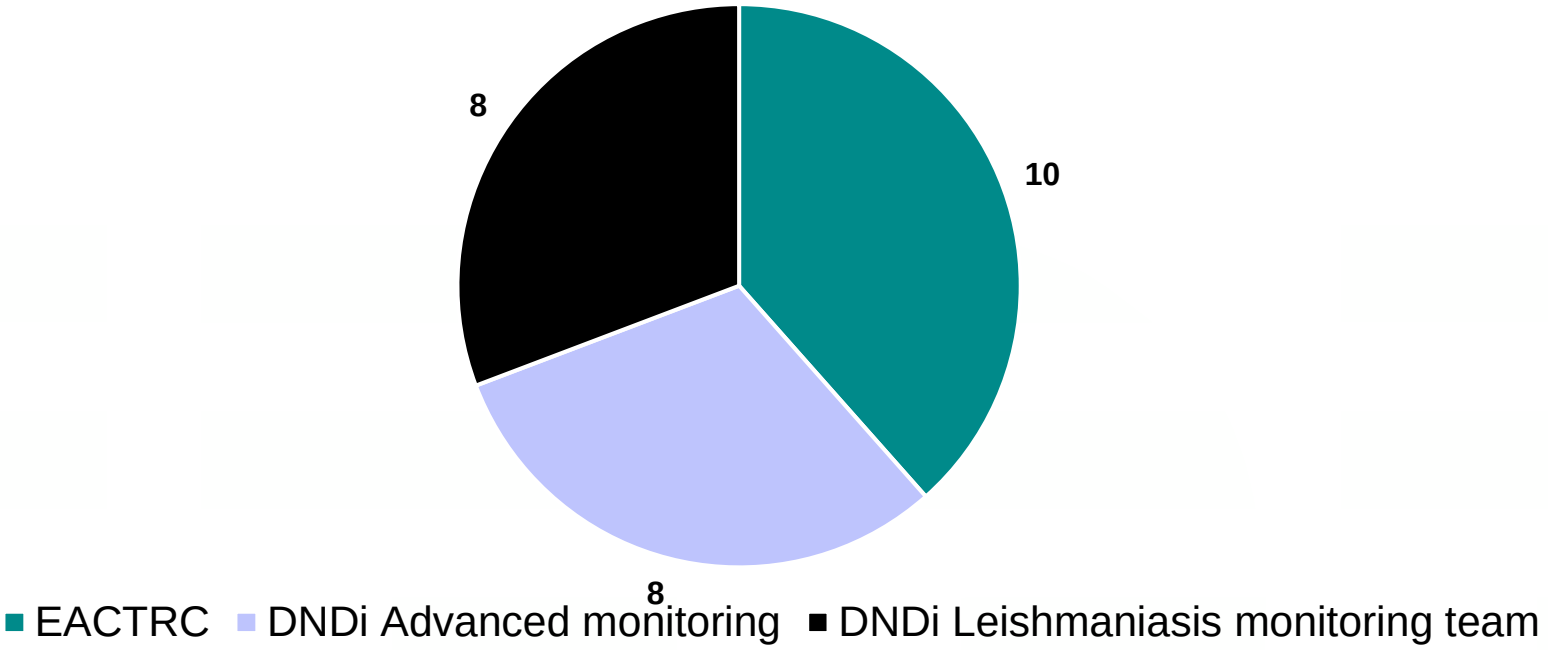
Specifically, we conduct the following:

- Project Management and Site Operations
- Clinical Research Training and Professional Development
- Quality Assurance *(trials site QMS development)*
- Physical infrastructure assessments *(Labs, Pharmacy, patient reception areas, samples storage)*
- Data Management
- Study Management
- Protocols, ICFs and and other Source documents development

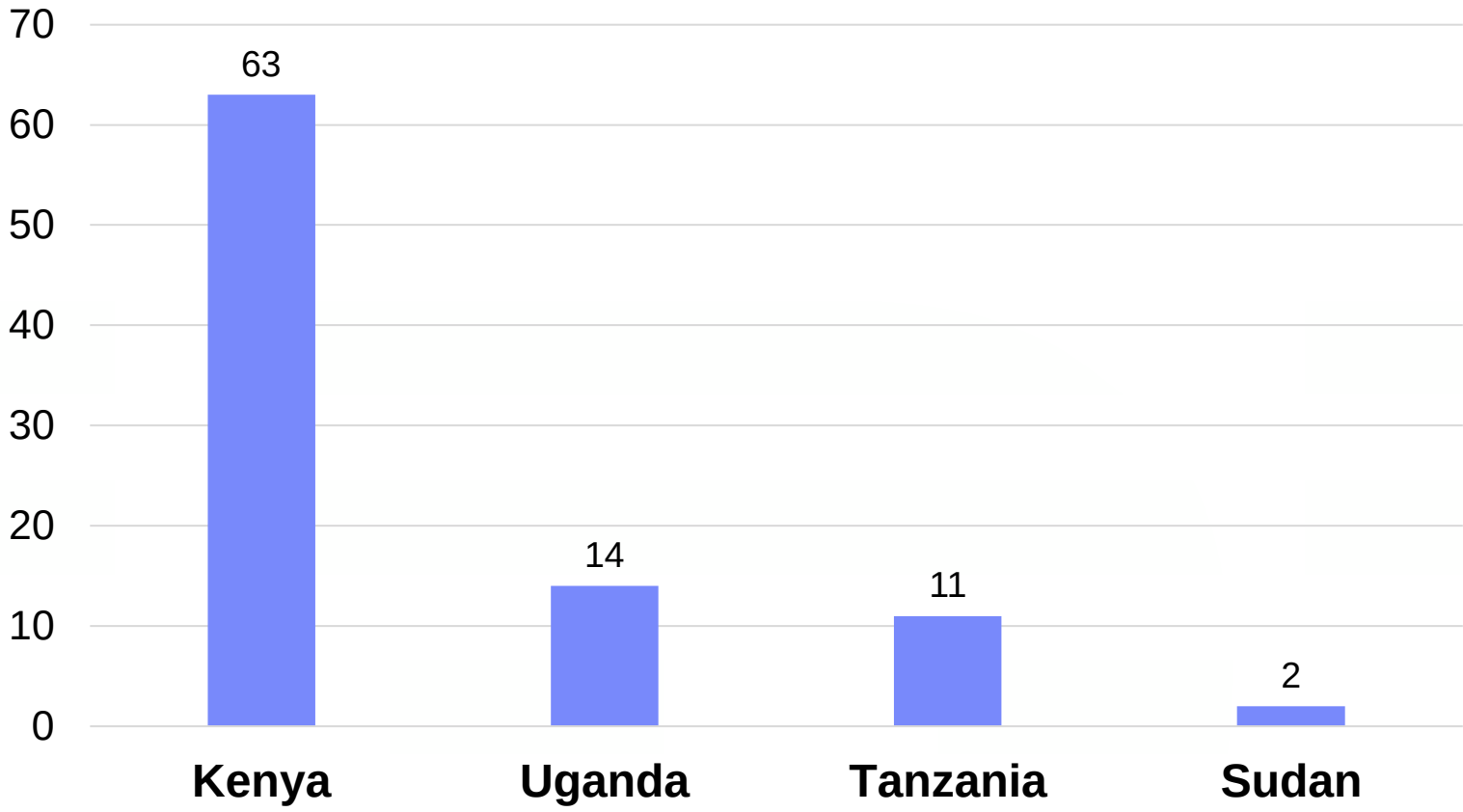
Total Number of Participants per Class 2018 - 2022



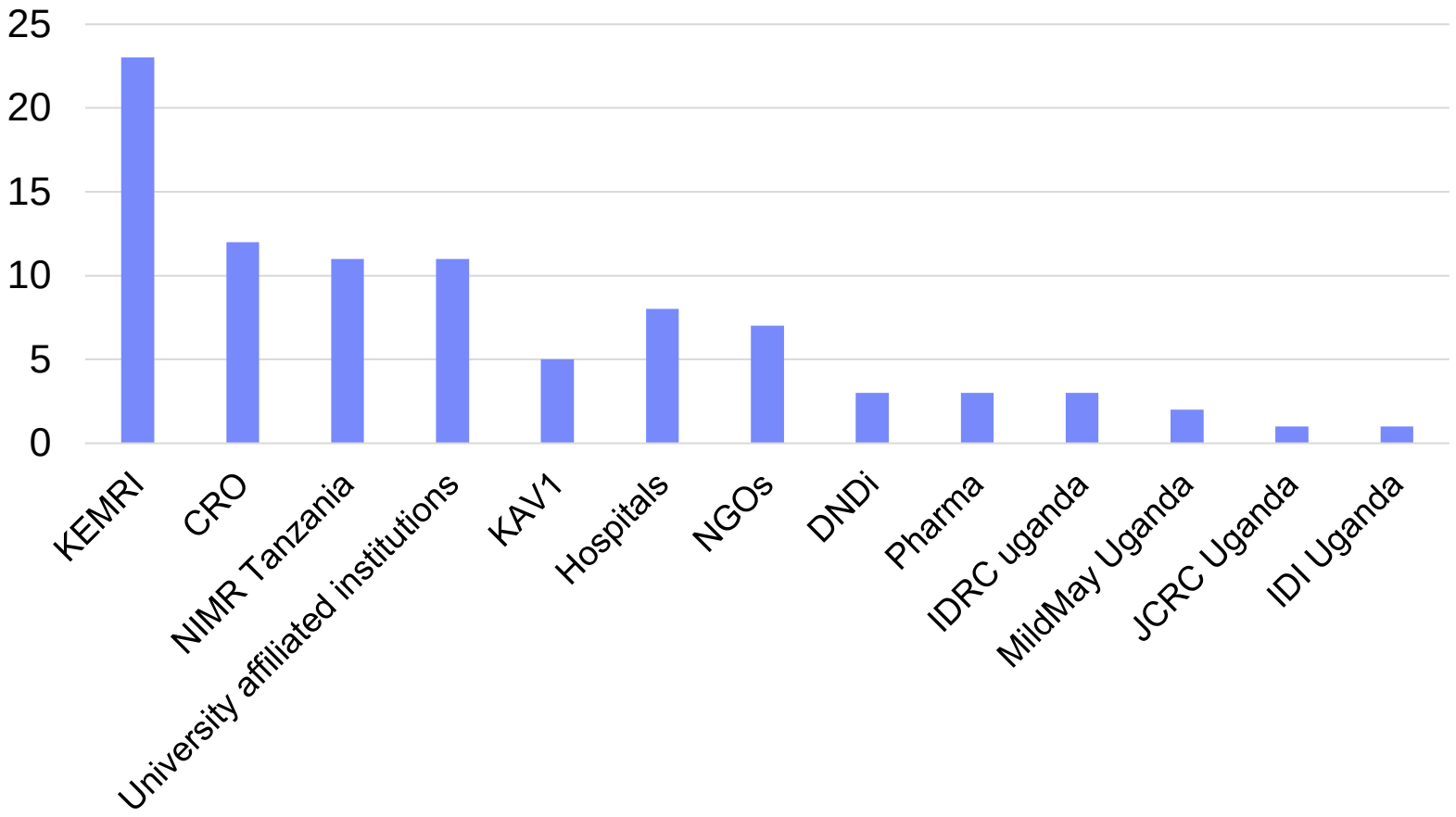
Advanced Monitoring Training
2018 - 2019
Total Trained = 26



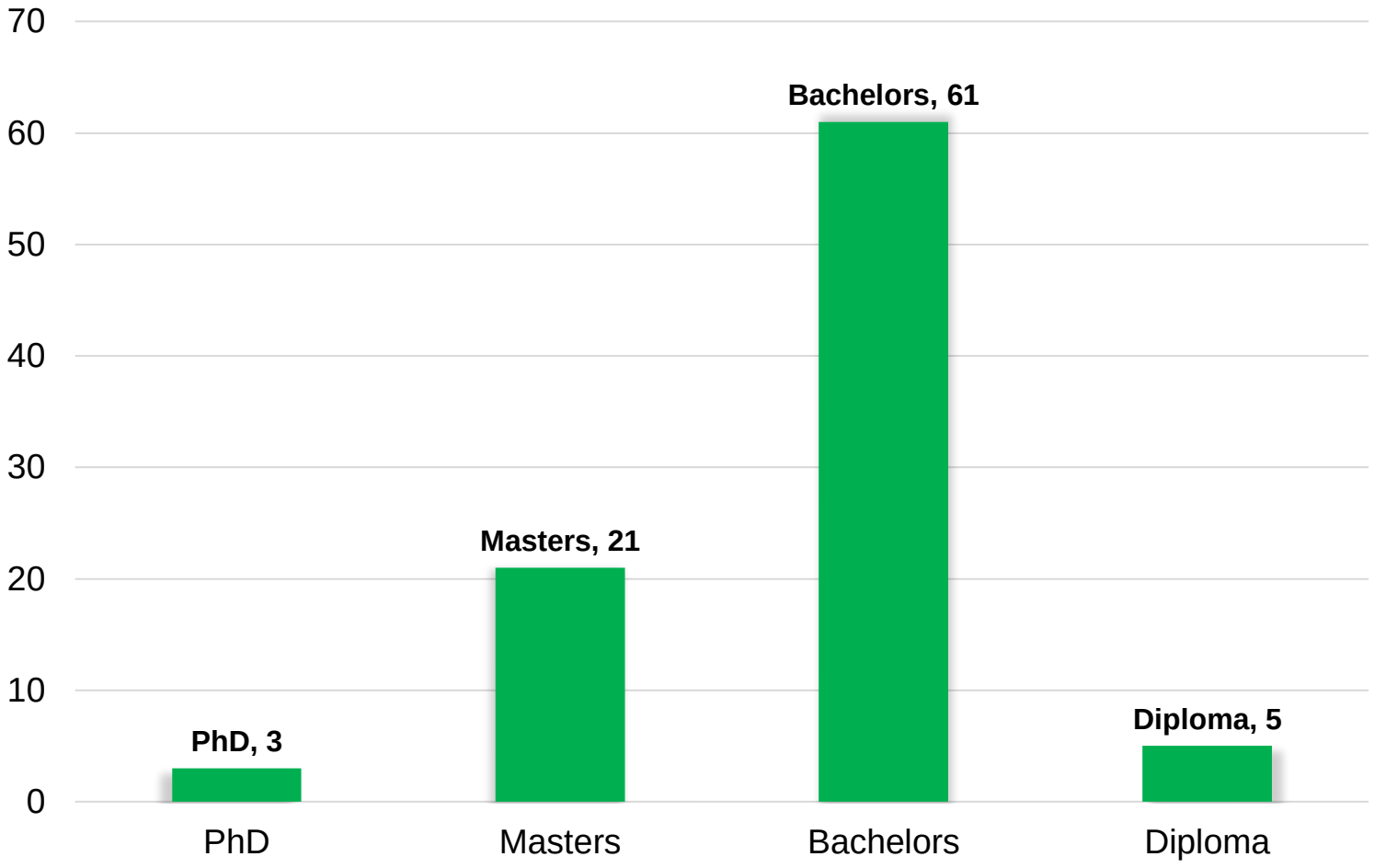
Country of Origin
Entry Level Clinical Monitoring Training
2019 - 2022
Total Trained = 90



Institution of Affiliation of Participants

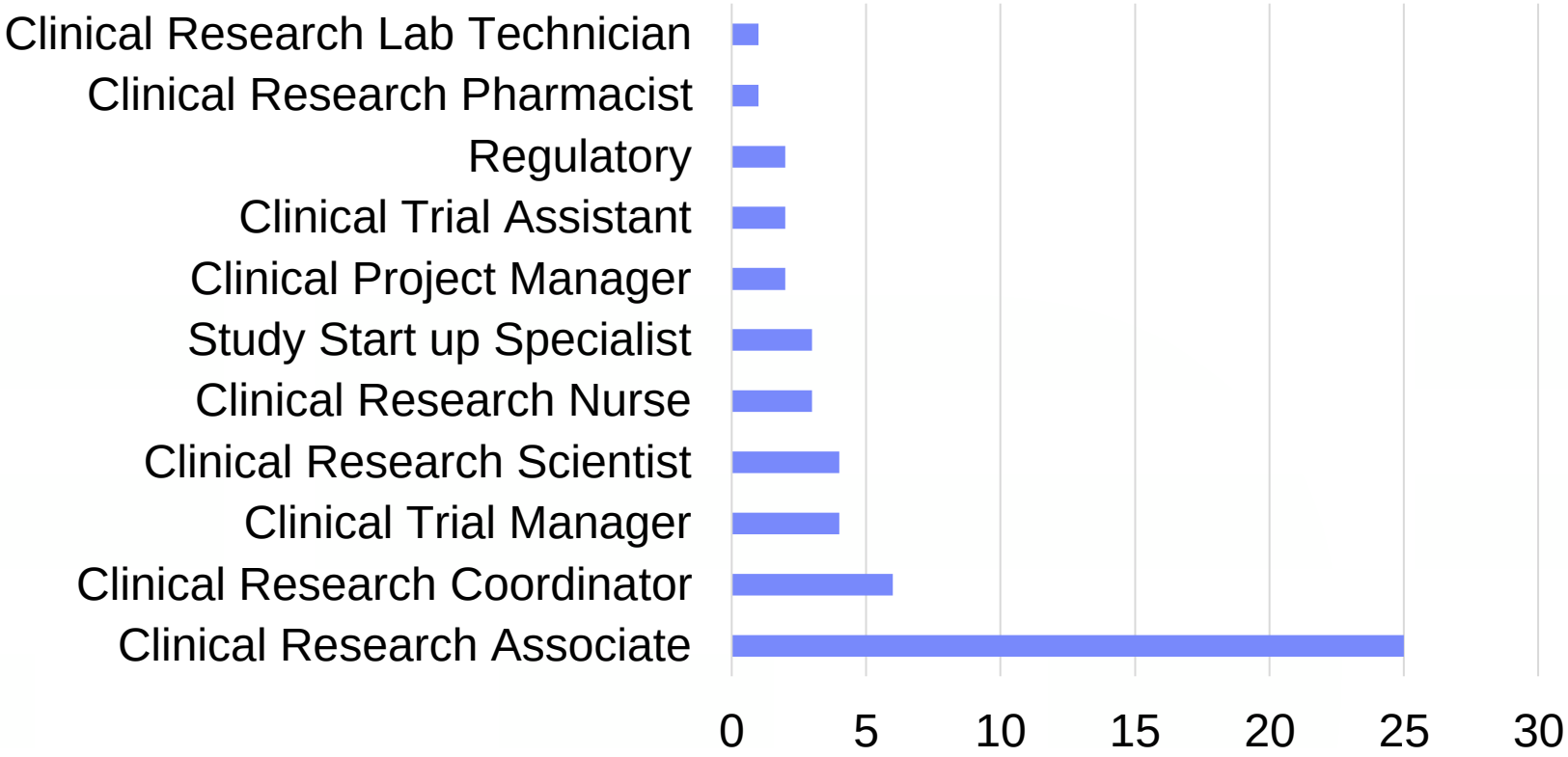


ACADEMIC QUALIFICATIONS OF PARTICIPANTS



Current Role after CRA Course

Total = 53



Successes

- Site staff and facilities needs assessment completed.
- Supports site and trial management
- On-site and web-based site staff training conducted.
- Entry level and advanced Clinical Trials Monitoring Training for site Monitors – with 90+ CRAs trained to date.
- Site staff training on GCP and HSP completed and documented.
- On-site monitoring and oversight
- Mentorship and internship for entry level clinical research professionals at CROs ongoing.
- Partnerships with local Universities to offer skilled based trainings.

Opportunities

- Partnership with medical schools to offer skill-based courses and academic programs – Msc, PhDs.
- Mentorship by experienced clinical researchers based at CROs, Pharma and AMC
- Student internships at CROs and other academic Medical centers
- Clinical Research Methods to be offered to all medical students
- Linkages with global clinical research training consortiums e.g. BlueCloud, CTTI, Transcelerate.
- Participatory learning Pre-qualification/Pre-site assessments.
- Investigator meeting and Site Initiation Visits .
- On-site/Remote monitoring visits adoption, training and support.

Proposed Next Steps ……..

- Invest in clinical research workforce development at all levels, from high schools Science clubs and Colleges.
- Identify training needs for existing clinical research workforce, offer relevant training and mentorship.
- Stimulate interest in clinical research enterprise among scientists and medical graduands.
- Provide legal and regulatory for certification of clinical research professionals.
- Form clinical research professional association.
- Offer internships to recent medical and allied life sciences graduates.
- Improved clinical research mentoring opportunities, both institutionally and individually.
- Improved career pathways for clinical researchers.
- Academy networks that can offer learning and support.
- Advocacy and research diplomacy to demonstrate the impact of clinical research.
- Increase health research funding from national governments as well as from international donors.

Thank you

www.Clinwinresearch.com