

Promoting responsible research processes using digital technology, and its impact on research conduct – an experience from Pakistan

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Pakistan



Research Regulation in Pakistan

- Drug Regulatory Authority of Pakistan (DRAP)
 - Biostudy rules 2017
 - Drug research rules
 - Clinical study committee
 - Licensing requirement for CROs, sites , sponsors - 2017
- Pakistan Health Research Council (PHRC) - National Institutes of Health (NIH)
 - National Bioethics Committee (NBC) – Ethics review committee (ERC)
- Institutional Review Boards (IRBs) or Ethics Review Committees (ERCs)
- No Mechanism for post approval oversight except progress reports requested by few ERCs including NBC ERC that rely upon transparency in investigator reporting



Organization Profile

Annual budget Rs. 28 billion (Year 2022)

Philanthropic spending to date Rs.

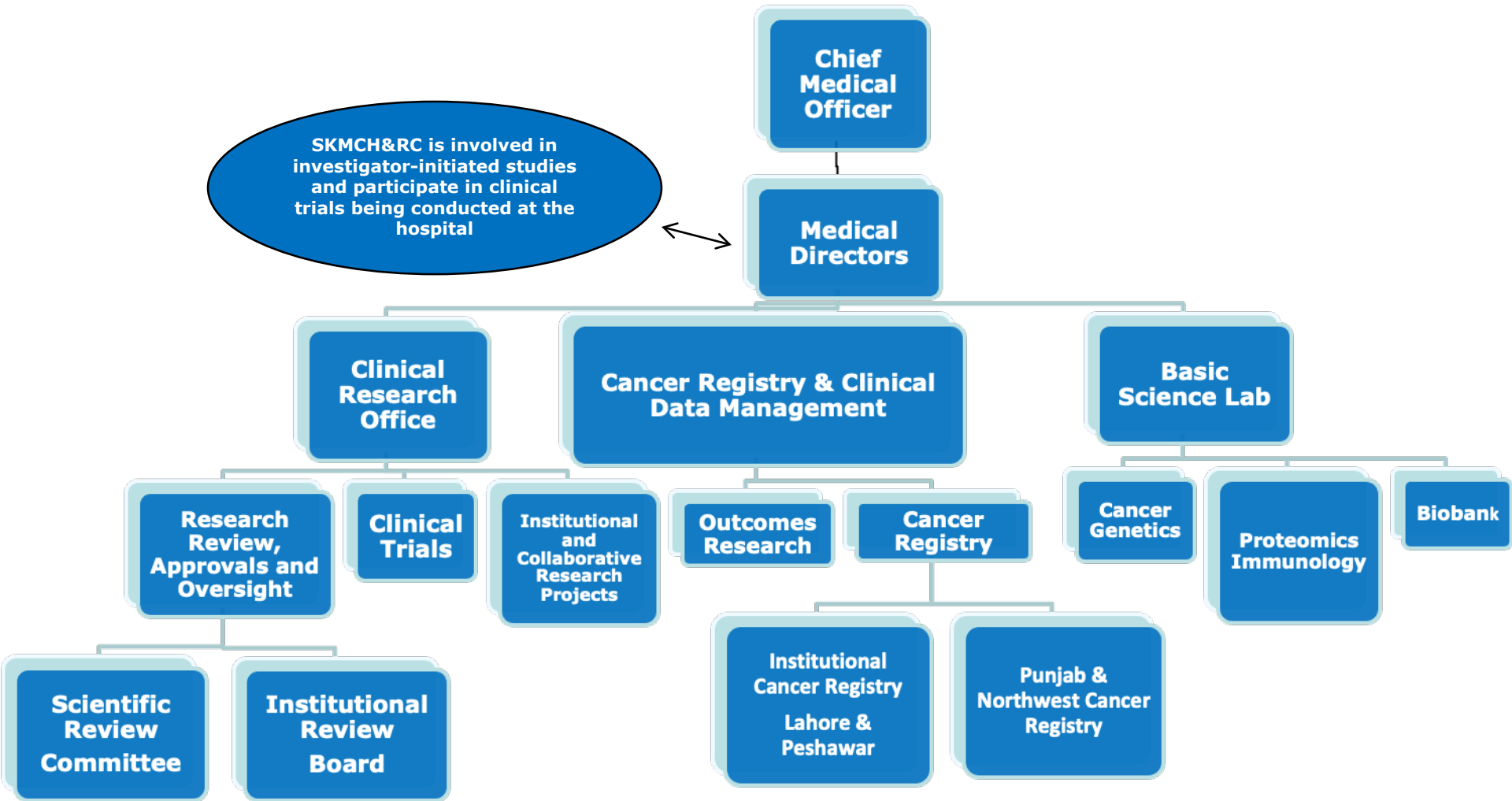
65.635 billion (US\$ 586 Million)

- Inpatient & ICU Beds 195
- New registrations 120,18
- Staff 3544

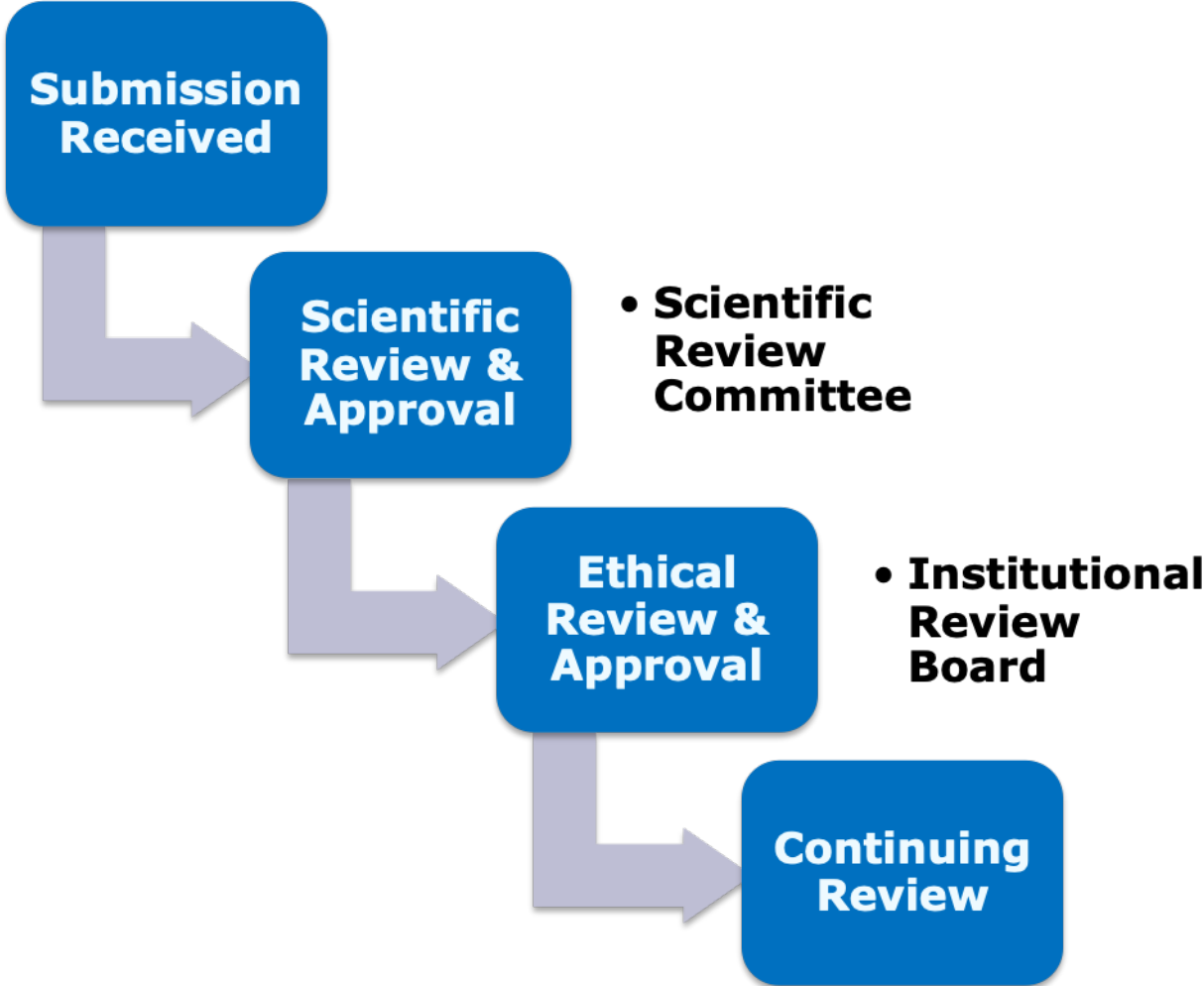
Hospital Mission Statement : “To act as a model institution to alleviate the suffering of patients with cancer through the application of modern methods of curative and palliative therapy irrespective of their ability to pay, the education of health care professionals and the public and perform research into the causes and treatment of cancer.”



Research Organization



Research Review and Oversight at SKMCH&RC



Research Compliance and Oversight Programme

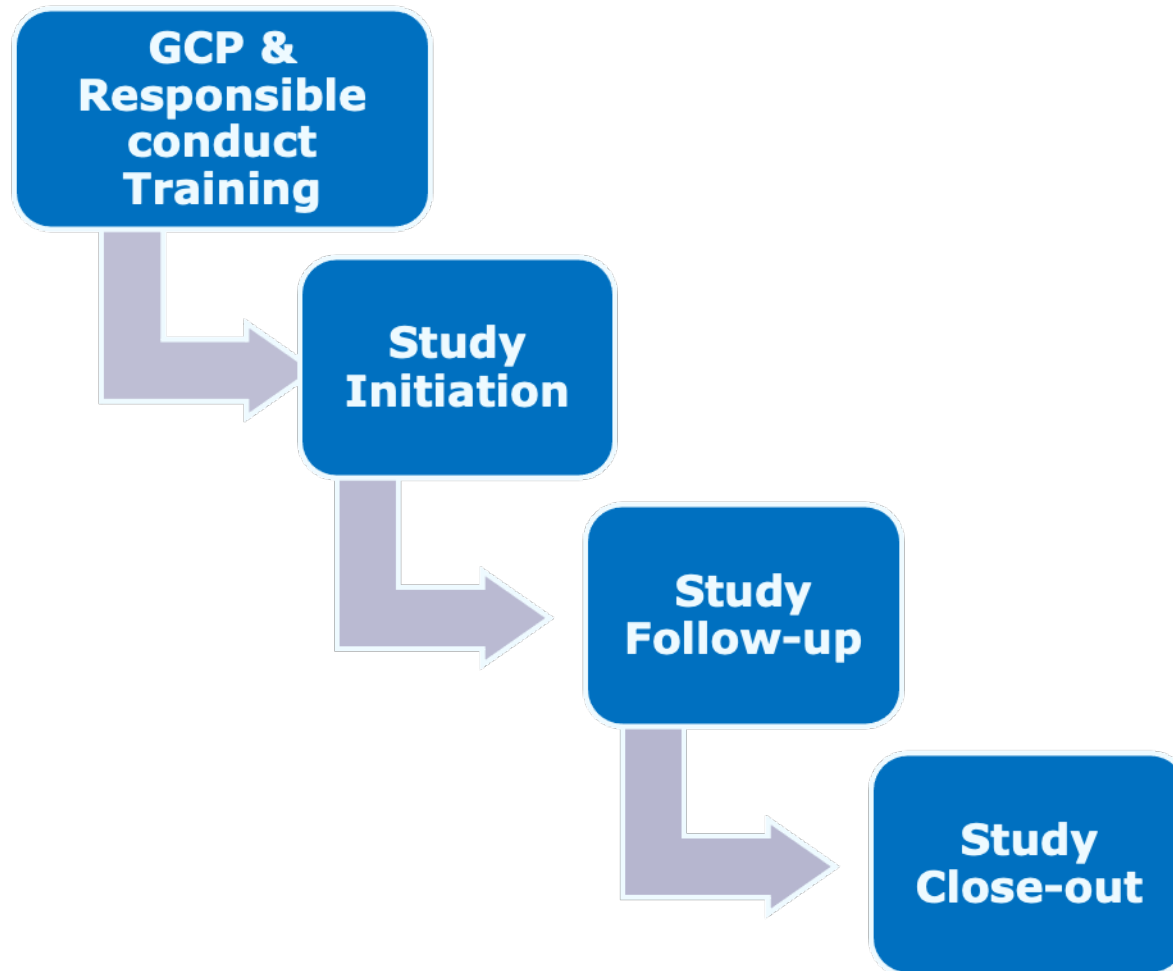
In 2018 SKM started a central research oversight and archival system, to promote compliance to ethics review standards and responsible research conduct

Investigators are provided with training of Research conduct on following aspects:

- ❑ Good Clinical Practice (GCP)
- ❑ IRB approvals & amendments notification
- ❑ Management of study records
- ❑ Consents process & its documentation
- ❑ Appropriate tasks delegation
- ❑ Conflict of interest & its management
- ❑ Quality Improvement Opportunity (QIO) & Adverse Drug Reaction (ADR) reporting



Oversight Process



Evolution during COVID-19 and beyond

- ❑ F2F sessions replaced by virtual meetings
- ❑ Initial informal discussions with investigators supplemented with video trainings and post training assessments. Additional open access online training resources adopted
- ❑ Use of structured templates, regular review of research records leading to timely identification of issues, root cause analysis (RCA) as well as corrective and preventive actions (CAPA)
- ❑ Periodic reviews ensured that identified issues are addressed systemically through changes in organizational policy and culture



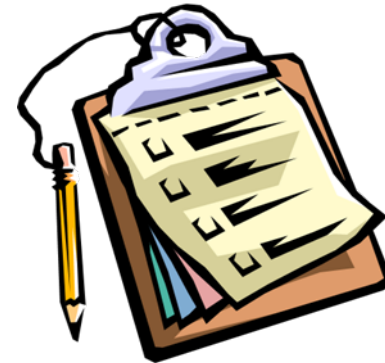
Demographics of Researchers

- A total of 141 studies were assisted through this system from April 2018 to November 2022.

		Frequency	
Gender	Male	75	56%
	Female	58	44%
Designation	Resident	72	58%
	Fellow	8	6.40%
	Consultants	14	11%
	Nurse	18	15%
	Others	12	10%
Previous Research Experience	Yes	18	16%
	No	123	84%



Programme Evaluation



Kirkpatrick Model

□ **Level I: Reaction**

How Does Participants feel about the training?

□ **Level II: Learning**

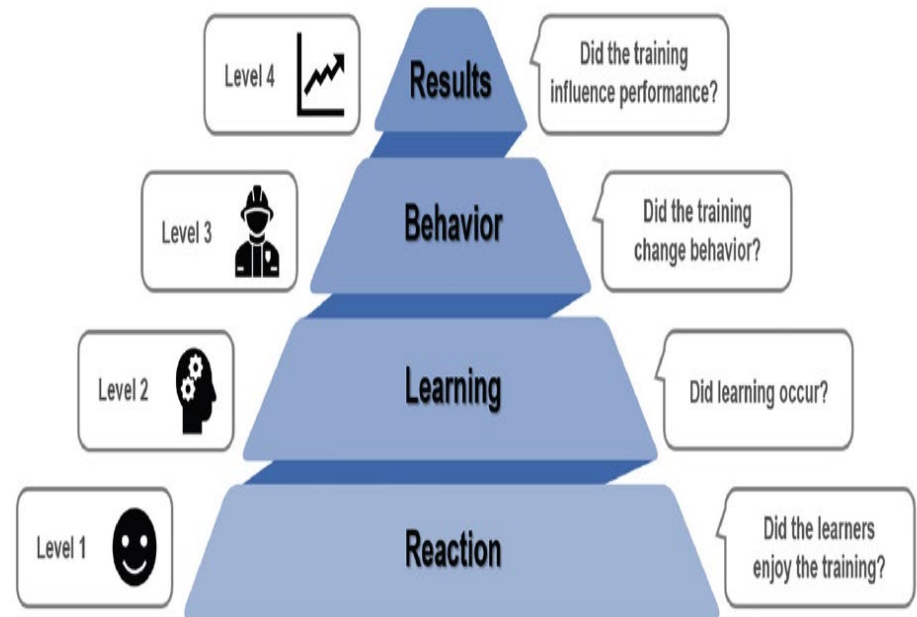
To what extend participants improve knowledge, skills & attitude

□ **Level III: Impact/ Behavior**

Impact of training, to what extend participants apply what they learned

□ **Level IV: Results**

Was it worth it ? Or is there a positive change in trainees?



Niemann L, Thielsch MT. Evaluation of Basic Trainings for Rescue Forces. Journal of Homeland Security and Emergency Management. 2020 Sep 1;17(3).



Reaction

For first level assessment 5-point Likert scale and open-ended questions were used.

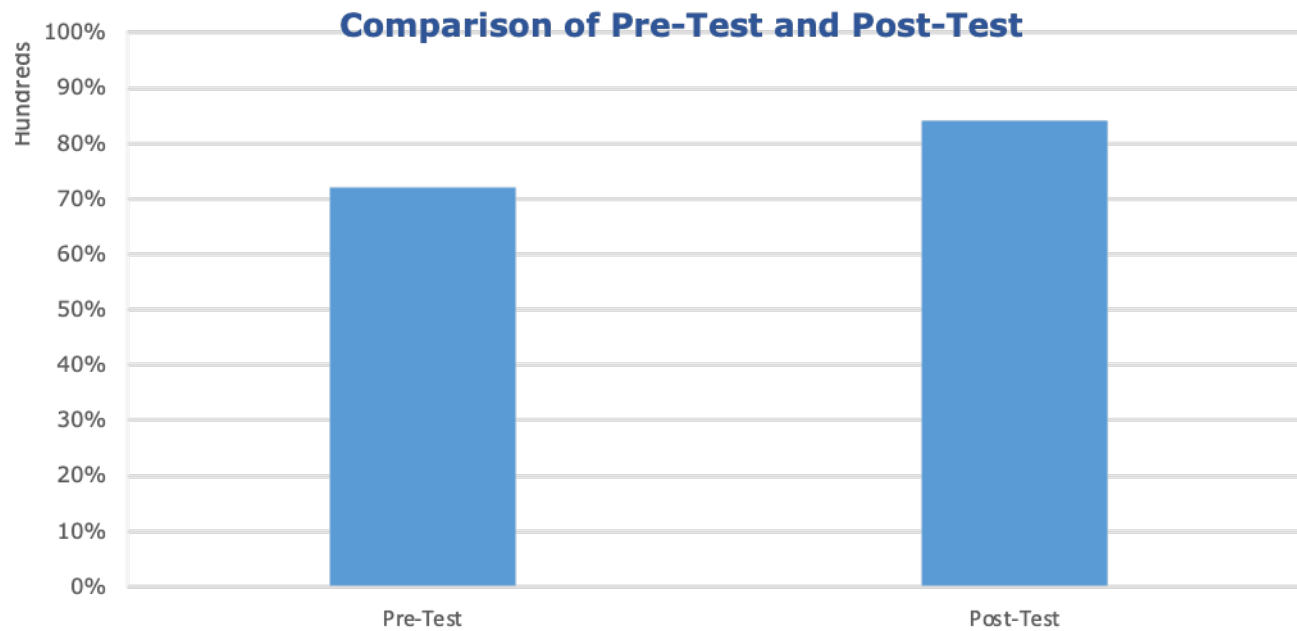
Quality of Training	Very Bad	Bad	Average	Good	Excellent
	0	0	0	29%	71%
Instructor's Effectiveness	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
	0	0	1%	20%	79%

No specific recommendation to improve the training program received from trainees.



Learning

Learning evaluation was done by pre-test and post- test.



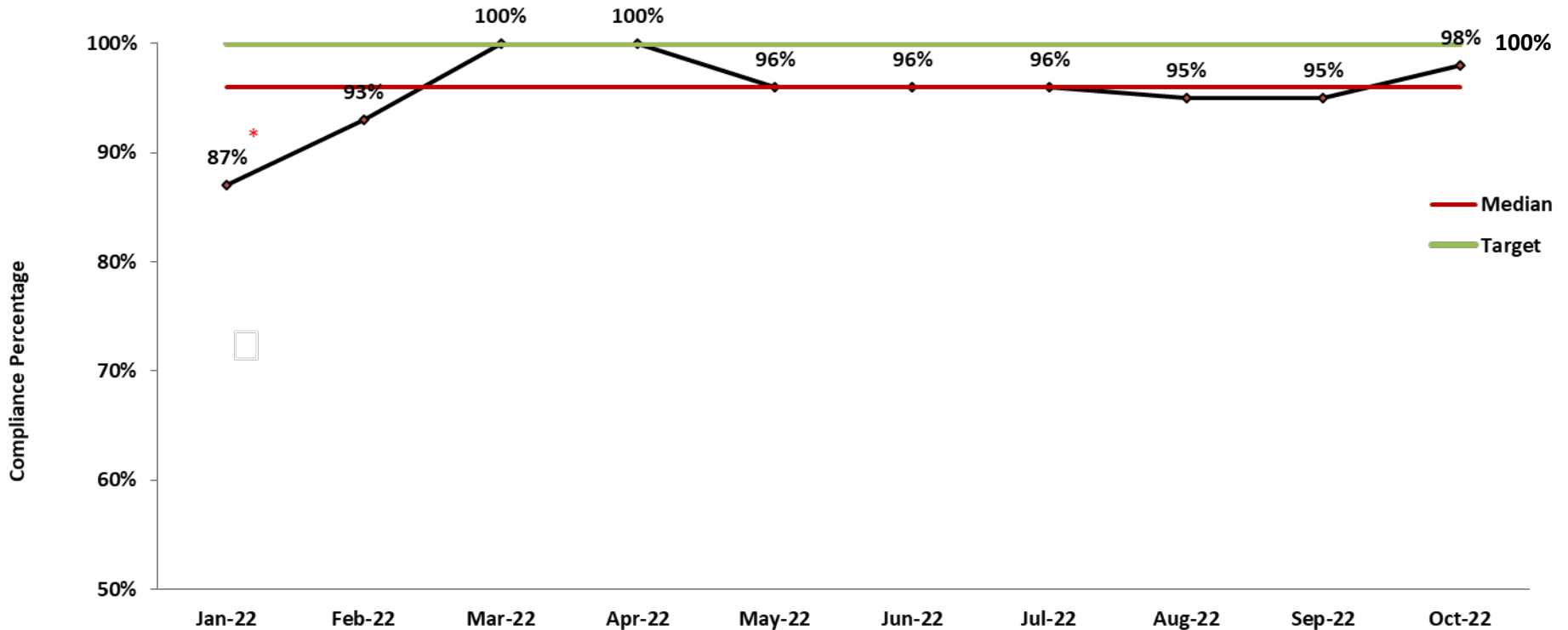
Behavior

We evaluated the third level based on key essential elements of training including proper consent documentation, appropriate task delegation, management of study team changes, protocol amendment approvals records management.

Sr.	Contents	Percentage Improvement		
		2020	2021	2022
1	Appropriate delegation of tasks	68%	76%	96%
2	Proper Consent Documentation	66%	79%	99%
3	Management of Team Changes	52%	73%	93%
4	Protocol Amendment Approvals	67%	98%	98.50%
5	Good Records Management	62%	93%	96%
6	GCP training	83%	89%	100%



Clinical Research
Ensuring all research studies are meeting essential requirements for record keeping
Target = 100%



Median = 96%
No. of Runs=4
Shift = 0

Trend = 0
Astronomical Point = 0

* This is a new indicator; department is working to improve compliance by focusing on investigator's training.

Challenges

- ❑ Shifting from informal trainings to formal training of investigators
- ❑ Balancing an advisory role and open communication while ensuring compliance
- ❑ Having defined consequences for misconduct but keeping the intent non punitive
- ❑ Human resource managing the programme : limited staff managing an expanding portfolio

Future Plans

We further aim to enhance Video Education Series to include training on

- ❑ Data Sharing and Ownership
- ❑ Good Publication Practices
- ❑ Research Misconduct



“IF YOU THINK TRAINING IS EXPENSIVE, TRY
IGNORANCE.”

and, remember, the definition of ignorance is repeating
the same behavior, over and over, and expecting
different results!

FOOD FOR THOUGHT!





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謝謝

धन्यवाद

Grazie

Tak

Благодаря ви

Ви благодарам

كل اركش

Orbigado

Merci

Thank
You

Bedankt

Thank
You

고마워.

Teşekkürler

Спасибо

Дякуємо

ありがとう