Report

On

Clinical Study Design for

Medical Devices and In Vitro Diagnostics

RIFC BRBC A BIRAC - Venture Center Initiative VENTURE CENTER birac Ignite Innovate Incubate

Tuesday - Thursday

8 – 10 August 2019

Venture Center,
100 NCL Innovation Park
Dr Homi Bhabha Road,
Pashan, Pune- 8

Contents

RIFC

Acknowledgment

BIRAC Regional Bioinnovation Center (BRBC) is stepping forward to filling up key innovation ecosystem gaps for Biotech/Biomed startups across the country and the second Venture Base Camp on Regulatory Processes and Certifications held from 8 - 10 Aug 2019 was a pleasing demonstration.

BRBC is thankful to the base camp logistics organizers, speakers, and participants.

Internal support: Logistics and management, Venture Center, Pune

Chetna D	Madhurima H	Pravin C
Deepa T	Neha K	Shiv T
Lipika B	Pallavi A	Vidhya B

External support: Photography and Videographer, IISER, Pune

Imavayan K	Vivek K

Financial Support

BIRAC Regional Bioinnovation Center (BRBC) at Venture Center, Pune

Venture Center, Pune

Organizer

Regulatory Information and Facilitation Center (RIFC) at Venture Center, Pune

Introduction

Venture Base Camps are high intensity, focused, theme-based camps intended to take a startup from point A to point B in their entrepreneurial journey, before their execution on key goals of the company.

The focus of this base camp was to frame the regulatory strategy and roadmap for medical devices in India.

This VBC was useful for innovators and startups in the following medical device categories: *Clinical grade screening, diagnostic and recording instruments* | *Medical devices for clinical intervention or treatment* |*Surgical tools and aids* | *Assistive devices or disability aids or image reconstruction or artificial body parts* | *Molecular in vitro diagnostics* | *Topical, surface and open wound contact products or products in body orifices* | *Implants made from polymers, body tissues, metal, plastic, ceramic etc*| *Sensors, IOT, Big Data, Mobile, Cloud, AI/ML, Analytics, decision support, software etc used for making medical decisions* | *Supplies & consumables used in diagnostics, preservation, hospital equipment* | *Recreational and popular diagnostics, wearable.*

Content

Focus:

To provide the first hand information in good clinical practice for designing, conducting, recording and reporting clinical investigations conducted in human subjects to assess the safety or performance of medical devices and clinical performance studies conducted to assess the clinical performance and safety of In Vitro Diagnostic (IVD) medical devices for regulatory purposes.

Hands on working on the actual documentation required for regulatory approval purposes and submitting to the Central Drugs Standard Control Organisation (CDSCO) and ethics committees viz., Clinical Investigation Plan, clinical performance evaluation plan or study protocol, Investigator's Brochure (IB), and Informed Consent Form

Base Camp outline:

Session 1	• Definitions, wording and its interpretation
Session 2	• Regulations involved in clinical studies
Session 3	• The role of statistics in clinical studies
Session 4	• Sample size calculations
Session 5	• Statistical analysis of data
Session 6	• Available clinical sites around Pune, and Timelines
Session 7	• Panel Discussion and Q&A
Session 8	• Ethical considerations (MDs and IVDs)
Session 9A	• Clinical investigation planning
Session 9B	• Clinical performance study planning
Session 10A	• Clinical investigation conduct
Session 10B	• Clinical performance study conduct
Session 11A	• Suspension, termination and close-out of the clinical investigation
Session 11B	• Clinical performance study initiation and closeout
Session 12A	• Responsibilities of the sponsor
Session 12B	• Quality and Auditing -- to evaluate conformity with the CPSP
Session 13	• Responsibilities of the principal investigator
Session 14	• Budgeting, and costing of clinical studies
Session 15	• Panel Discussion

Attendees:

47 people from different cities participated in the base camp. Attendees represented a variety of organizations, with the largest to smallest numbers from the startups, technology business incubators, academic sector, not for profit hospitals and research institutes.

Evaluation:

During the base camp, the intentions were met; there was an exchange of information on regulatory obligations for the medical devices.

Rating Scale			
1	Bad	2	Well below average
3	Below average	4	Average
5	Good	6	Very Good
7	Excellent		

	Category	**Avg (Max-Min) Count**
Section 1 - Event administration & facilities(Please tick)		
1	Quality of pre-event (registration, queries)	6.0 (4,7) 34
2	Quality of Staff responsiveness	6.4 (5,7) 34
3	Pace of the event (time mgmt)	5.7 (3,7) 34
4	Quality of food & beverages	5.7 (3,7) 34
5	Venture Center facility (Was it appropriate, clean & comfortable?)	6.3 (5,7) 33
6	Overall satisfaction with event organization	6.1 (4,7) 33
Section 2 – Sessions & lectures Day 1,2,3		
1	Definitions, wording & its interpretation	6.1(3,7)33
2	Regulations involved in clinical studies	6.1(3,7)33
3	The role of statistics in clinical studies	6.1(3,7)33
4	Sample size calculations	6.3(4,7)33
5	Statistical analysis of data	6.4(5,7)33
6	Available clinical sites around Pune, & timelines	6.1(5,7)33
7	Panel discussion & Q & A	6.2(5,7)32
8	Ethical considerations(MDs &IVDs)	6.1(4,7)32
9	Part-1 Clinical investigation planning	6.2(5,7)30
10	Part-2 Clinical investigation planning	6.2(5,7)30
11	Clinical investigation conduct	6.2(5,7)29
12	Suspension, termination & close out of clinical investigation	6.1(5,7)29
13	Responsibilities of the sponsor	6.2(5,7)30
14	Part-1 Clinical performance study planning	6.3(5,7)26
15	Part-2 Clinical performance study planning	6.3(5,7)27
16	Clinical Performance study conduct	6.2(5,7)27
17	Clinical performance study initiation and closeout	6.0(5,7)28
18	Quality & Auditing to evaluate conformity with the CPSP	5.9(4,7)28
19	Responsibilities of the principle investigator	6.2(5,7)29
20	Budgeting, and costing of clinical studies	6.1(4,7)31
21	Panel Discussion	6.5(4,7)31
22	One-to-one discussion with experts	6.7(6,7)20
3	**What did you enjoy the most**	
1	The speakers were very friendly and appropriate. The Workshop helped justify the regulatory stigma for me.	
2	The group of speakers, the diversity, the mix of young entrepreneurs & mentoring from Dr. Ghooi & Navnath sir.	
3	Management of the event, pre-event online communication.	
4	Panel Discussion	
5	Clinical plan design	

6	Designing the clinical Investigation Plan.
7	Everything
8	All the sessions ware very informative & one to one is the best.
9	Panel Discussion
10	Budgeting & Costing Session.
11	Ambience, Easy Understandable Presentation.
12	Insights from KOLs on conducting Performance evaluation effectively.
13	Networking, one to one.
14	The Subject is new to me, there are many queries has been resolved on road map.
15	Interaction & all the talks with speakers.
16	One to one discussion.
17	Knowledge of speakers & their honesty about state of medical device & regulations in India.
18	Interactive Session & Panel Discussion.
19	Very friendly, Open & Experience limit to get knowledge & expertise.
20	Diversity of the participants & Interaction with Speakers.
21	Panel Discussion got more clarification.
22	Panel Discussion
23	Panel Discussion
24	Biostatistics & IVD Presentation.
25	New contacts & networks got to know the facilities & service of venture Center.
26	Speakers were up for Interactive Discussion.
27	Content & explained Very Well.
28	IVD Section/Day-2
29	Prof.Ghooi's & Prof.Paranjape, Dr.Bhatt, panel discussion Premnath Sir were really great.
30	Opportunities to meet the experts, All experts have been so cordial & have shared valuable inputs that have helped us get clarity around clinical evaluation.
31	Interacting with other participant, regulatory & Clinical Protocol process.

4	**Please suggest a topic on which you wish to have a workshop on?**
1	Core Workshop on clear C/D medical devices replacing from PoC to manufacture of non notified device.
2	Licensing authority (central/State) spokesperson from the CDSCO committee.
3	More focus on pilot& pre pilot.
4	How to deal with certifications & regulatory & non-invasive & non-notified devices.
5	Fund raising
6	CSDSO guidelines are most confusing. So a people understanding are very helpful.
7	One complete example of Clinical Study.
8	Clinical Studies.
9	13485:2016; CE mark as per MDR/IVDR;US FDA SID(K) Process;
10	Satisfied for clinical study.
11	Product development-Medical Device
12	Heart rate variability and its application.
13	Medical device Regulation for 2 Days.
14	Marketing & Sale of MD.
15	Academic Clinical Trial.
16	On clinical trials on MD's/etc.
17	How to design a MD Considering ISO Standards.
18	Specific Workshop on IVD(not device+IVD)
19	Regulations (INDIA)

20	Can you involve Practitioner Medical facility had believe in Innovation.
21	Regulation & Auditing clinical Trial Pace (Medical Device)
22	Pre clinical trials (Animal) One-on-one session on Medical Device specific expert like ortho/cardio/ophthal,etc.companies/medicos to understand path.
23	For CE & WHO-handling, Lectures to start biobanking/Lab facilities.
24	regulatory & Marketing, Product design & Development.
25	Sessions from clinical indicating pain points for various medical conditions that they wished to have solutions around.
26	Being Commercial ready (what are the regulatory challenges)

5	**How did you hear about the Workshop?**
1	Email-13
2	Colleagues
3	Social media
4	Others
5	Twitter/Website
6	Social Media
7	Navnath/Ashutosh
8	Through Mentor.
9	Through Mentor & friend.
10	Through BIRAC.
11	Social Media
12	Navnath
13	By BIRAC correspondence.
14	Mostly focused towards clinical trials of drugs & not much into IVD's.
15	Mail from VC
16	Others
17	Email from BIRAC
18	Venture Center/friends
19	Through VC
20	BIRAC

6	**Would you attend similar workshop on these topics?**								
		YES	30	NO	0				
7	**Is 3 days too long for a workshop?**								
		YES	3	NO	28				

8	**What changes would you like to be seen in the next base camp**
1	Discussion with more experts.
2	Kindly provide us Wi-Fi facility.
3	Site tour
4	One complete example of clinical study.
5	Good format/may be inclusion of Regulatory people if possible.
6	Q & A should be strictly restricted to after seminar. Too much time wasted listening to personalized experience from participants.
7	Free slot to work on assignment.
8	Provide all the PPT before hand, We can have informal discussion.
9	Keep up the good watch & long questions at the end of talk.
10	Not really.
11	since we came from outside & stayed @hotel. We tend to take breakfast there so we could wrap breakfast in morning.
12	First seating area was not comfortable, 2nd in MD there should be some examples in the PPT, 3rd MD also use

	mechanical parts, so, how to make according to standards & where to make.
13	Drugs & IVD regulations are different so lecture should be more towards IVD.
14	Better Food
15	Hall seating arrangement.
16	Target Resource Persons/speakers.
17	VC Visit for guest (Participants outside VC)
18	half a day for lab facility visit of Venture Center, so that start ups manufacturer could use facility of Venture Center.
19	One to One meeting is very good concept, but it should give more time.
20	Time management
21	This was a very well organized camp. first one that I attended, I am not sure what in one to be changed.
22	Information from Participant, Questionnaire to be collected to make session.

List of speakers & Mentors

Sr	Name	Affiliation
1	Aniruddha Atre	Jeevtronics Private Limited, Pune
2	Arun Bhatt	Consultant – Clinical Research and Development, Mumbai
3	Chitra Lele	Sciformix Technologies Private Limited, Pune
4	Deepti Goel	Harrison's Tech Consultants, Mumbai
5	Madhur Motwani	Jehangir Clinical Development Centre, Pune
6	Manjiri Joshi	Covance Inc. India, Pune
7	Navnath Kadam	Venture Center, Pune
8	Pathik Divate	Jehangir Clinical Development Centre, Pune
9	Premnath V	Venture Center, Pune
10	Priya Nagaraj	Venture Center, Pune
11	Ramesh Paranjpe	National AIDS Research Institute, Pune
12	Ravindra Ghooi	Scientia Clinical Services, Pune
13	Sanish Davis	Covance Inc. India, Pune
14	Sharayu Paranjpe	Cytel Statistical Software & Services Private Limited, Pune
15	Vishwas Sovani	Pharmawisdom, Pune
16	Yashesh Mehta	Sciformix Technologies Private Limited, Pune

List of participants

Sr	Name	Affiliation
1	Abel Arun NS	Indian Institute Of Technology Madras
2	Abhijeet Bhagat	Atmen Technovention Private Limited
3	Aditi Purandare	Embryyo Technologies Pvt Ltd
4	Ajay Sangwan	Nyokas
5	Ajay Suryavanshi	Nayam Innovations Pvt. Ltd.
6	Amey Haldankar	Ayu Devices Pvt Ltd
7	Apoorva Bedekar	Cordwood Technologies LLP
8	Bharti Dhaundiyal	Betic
9	Dilip Shankar	Incubate At C-CAMP
10	Divyakshi Kaushik	SIIP Fellow Venture Center, Pune
11	Chirag Pandya	Ampligene India Biotech Pvt. Ltd.
12	Sumit Mediratta	Sumit Mediratta
13	Ekta Khattar	Voxtur Bio Ltd
14	Gaurav Batra	Translational Health
15	Gayathri Iyer	Scandinavian Meditech
16	Gururaj Rao	International Stemcell Services Ltd.
17	Harikishan Shetty	Rajamadhangi Medical Technologies Pvt Ltd
18	Jilma Peruvangat	Kozhnosys
19	Jyoti Kumbhar	Intignus Biotech
20	Kumari Priyanka	Bionic Hope Private Limited
21	Llewellyn Dsa	Bionic Hope Private Limited

22	Lokap Sahu	On My Own Technology Pvt. Ltd.
23	Lubaina Koti	Kozhnosys
24	Mayil Vahanan Bose	Cancer Institute(WIA)
25	Mehul Baldwa	Prayas Fellow
26	Mehul Deepak Chheda	Scandinavian Meditech LLP
27	Mohammad Samheel	Osind Meditech Pvt Ltd
28	Neeraj Kumar	Crimson Healthcare Pvt. Ltd.
29	Niketa Dinesh Chauhan	Synthera Biomedical Pvt. Ltd.
30	Nikhil Das	Sedign Solutions Pvt. Ltd.
31	Nishant Kathpal	Ayati Devices Pvt. Ltd.
32	Phani Chintalapati	VIHATI TECHNO HEALTH PVT LTD
33	Pramodkumar Bajaj	Sperm Processor Pvt Ltd
34	Prashant Singh	Genelek Technologies Pvt. Ltd.
35	Preeti Nigam Joshi	Fastsense Diagnostics
36	Rahul Bajaj	Sperm Processor Pvt Ltd
37	Rohini Krishnamoorthy	Sensivision Health Technology
38	Saiprasad Poyarekar	Pacify Medical Technologies Pvt Ltd
39	Sandeep Dahake	Precisurg Private Limited
40	Shahrukh Khan	KIHT, AMTZ, Vizag
41	Sreekar Kothamachu	Nesa Medtech Pvt Ltd
42	Sriram Vemulapalli	SIPRA LABS LTD
43	Swati Shukla	Biolmed Innovations Pvt. Ltd.
44	Tanuj Gigras	Nayam Innovations Pvt Ltd
45	Udit Bokaria	Achira Labs Pvt Ltd
46	Vaishnavi Kulkarni	Intignus Biotech
47	VISHNU PRADEEP	Waferchips Techno Solutions Pvt Ltd

Photo Gallery

https://photos.app.goo.gl/WBeeqbcxdAQYZ6fM7

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