



# Indian Society for Clinical Research

## *Presents*

### A Workshop on “Data Anonymization”

St. Mark’s Hotel, 4/1, St. Mark’s Road, Bengaluru, Karnataka, India

23<sup>rd</sup> November 2019

**Highlights:** While the global landscape of clinical data sharing is becoming prominent day by day, it is becoming challenging to store, mine, and analyze heterogeneous data across multiple data sources and multiple regions. Proactive sharing of clinical trial data has been a key strategic aim since last few years. Data must be shared in such a way as to ensure the protection of patient privacy. Whilst this is the foremost priority in any data sharing exercise, the changing technology is increasingly challenging the ability to share data in enough depth and detail. This workshop is going to explore how anonymization of internationally sourced clinical trial data may be achieved while maintaining the scientific utility of the data. This one-day workshop is designed to enable the participants to gain more insights on data anonymization from programmers’ perspective. It will also highlight the Biostatistician’s role in data anonymization and the various ways it helps the clinical research community.

**Who Should Attend:** Statistical Programmers working with Pharmaceutical Industry or Contract Research Organizations, Biostatisticians, Medical Writers, Clinical Scientists, Clinical Data Managers, Investigators, Research Scholars or Scientists interested in Clinical Research, HealthCare Professionals from Government Agencies, Non-profit Organizations/Associations and Academia, and Medical, Pharmacy, Statistics or Life-science Students or Professionals interested in Clinical Research.

<b>Convener:</b> Rajesh Kher (Janssen)		
<b>Chairperson:</b> Gaurab Chakraborty (Covance)		
<b>Scientific Committee</b>		<b>Local Organizing Committee</b>
Pinakin Jani (IQVIA)	Mriganka Dutta (Covance)	Neha Srivastava (Covance)
Anadya Prakash Tripathi (Abbott)	Krishnendu Biswas (Novartis)	Vijaya Lakshmi G (Covance)

Data Anonymization - Workshop by ISCR St. Mark's Hotel, 4/1, St. Mark's Road, Bengaluru, Karnataka, India 23rd November 2019		
Date	Time	Topic
Saturday, 23rd November	08:30-9:30	Registration
	09:30-10:00	Introduction & Welcome note
	10:00 - 10:45	Efforts by Regulatory Agencies towards Data Transparency
	Tea Break (10:45-11:15)	
	11:15-11:45	GDPR Requirements - How much do we know?
	11:45-12:30	Data Anonymization - Are your efforts worth it?
	Lunch Break (12:30-13:30)	
	13:30-15:00	Data Anonymization - Programming Perspective
	15:00-15:45	Data to Document Anonymization- Channelizing the Synergies
	Tea Break (15:45-16:15)	
	16:15-17:00	Data Anonymization - Boon for Research Advancements
	17:00-17:30	Closing remarks

ISCR SPONSORSHIP CATEGORIES*				
Sponsorship Offerings	Platinum Sponsor Rs. 50,000	Gold Sponsor Rs. 30,000	Silver Sponsor Rs. 15,000	Sponsor for Kit-Bag Rs. 50,000
Complimentary Table /Booth Space at Venue **	Yes (Medium)	Yes (Medium)	No	Yes (Medium)
Free Delegate Registration	Five**	Three**	One	Three**
Logo on Flyer	Yes	Yes	Yes	Yes
Logo on Standees/Banner	Yes	Yes	Yes	Yes
Logo on Delegate Kit	No	No	No	Yes
Promotional Material on Delegate Tables	Yes	Yes	Yes	Yes

ISCR is the sole sponsor of this event;

\*\*Two additional free registrations in lieu of table/booth space

### Registration Details (Fees in INR):

Students	Academia	ISCR Members	Non-Members
Rs. 1500.00	Rs. 2000.00	Rs. 2500.00	Rs. 3000.00

#Group registration discount: 1 free in a block of 5 registrations

Online Registration: <http://www.iscr.org/events-registration/>

Online Payment: <http://www.iscr.org/payment-events-workshops/>

**Offline Payment:** Cheque/DD payable at Mumbai should be made in favor of “Indian Society for Clinical Research” & mailed to us at ISCR Secretariat, c/o Pfizer Limited, The Capital 1802, 18th Floor, Plot No. C-70, ‘G’ Block, Bandra Kurla Complex, Bandra (E), Mumbai-400051

**For any query, please contact ISCR on [Email: info@iscr.org](mailto:info@iscr.org) Telephone: +91-8454827775**



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### Speaker Biographies and Presentation Topics



#### Efforts by Regulatory Agencies towards Data Transparency

**R. Gunasekaran**, Associate Director – Biostatistics, IQVIA,  
Bengaluru.

R. Gunasekaran is a Master in Biostatistics from Christian Medical College, Vellore. He has over 15 years’ experience in clinical research across Pharma and CRO. He has over 20 publications in various international journals. He is certified in Executive General Management from IIM, Bangalore. He is a champion in change management and seasoned process improvement professional. His interests include teaching and travel.



#### GDPR requirements – how much do we know?

**Priya Rajagopal**, Head CDOC-B (Clinical Development Operations Center Bangalore), GlaxoSmithKline Asia Pvt Ltd

Priya Rajagopal is a Masters in Statistics from Bangalore University and has obtained Post Graduate Diploma in Operations Management from Symbiosis University. She is a PhD scholar at Alliance University and is doing research in Systems and Operations Management. She has over 17 years of experience in Clinical research. She has started her career as a Biostatistician and went to manage a team of statisticians and programmers and now is the site lead for the Vaccines unit in Bangalore. She is a first rank holder and gold medalist in MSc. One of her values is to keep learning, as she strongly believes that there is never an end to learning and one can truly grow as an individual by enriching oneself with knowledge. She has earned a Six sigma black belt from Indian Statistical Institute. Apart from being curious on emerging trends in Clinical research, she is very passionate about coaching people and developing them. She has successfully mentored many Statisticians and Stat programmers over the years who have reached great heights in the industry.





### Data Anonymization – Are your efforts worth it?

**Vijayalakshmi Gajulapalli, Senior Manager, Biometrics, Covance, Bangalore**

Vijayalakshmi has worked in Pharma and CRO for around 12 years and has worked with pharmaceutical firms like Novartis and Novo Nordisk. She has extensively worked on CDISC standards in both SDTM and ADaM and is also serving as a subject matter expert for Regulatory Submissions. She has a Bachelor's degree in Statistics & Computer Science and a Master's in Business Administration.



### Data Anonymization - Programming Perspective

**Nepal Madhireddy, Statistical Programmer, Covance, Bangalore**

Nepal has more than 5 years of experience as a Statistical Programmer. He has experience in Therapeutic areas like Neurology and Oncology and has worked with PAREXEL prior to joining Covance, Bangalore. He has completed his Bachelor's degree of Pharmacy from St. Peter's Institute of Pharmaceutical Sciences.



**Kaushik Sundaram, Statistical Programmer, Covance, Bangalore**

Kaushik is a statistical programmer working with Covance, Bangalore. He currently handles programming activities for Data Anonymization. He received his Bachelor's degree in Computer Science Engineering from RNS Institute of Technology, Bangalore.



### Data to Document Anonymization- Channelizing the Synergies

**Dr. Rajesh Pandey, Offering Head-Medical Writing, Tata Consultancy Services Limited, Life Sciences.**

Dr. Rajesh Pandey is a Physician with MBA in Healthcare and has around 20 years of industry experience. Currently, he is working as Head of Medical Writing at Tata Consultancy Service and is responsible for competency development in Medical writing and defining & developing strategy for Medical writing domain to develop innovative solutions for the domain.

His Medical writing experience spans across Regulatory writing, Clinical Trial Disclosures, Aggregate Safety Reports, Medical affairs as well as Medico marketing segments. He has an excellent track record in successfully leading several challenging medical writing projects.

He has worked for Medical Writing assignments for more than 30 different global as well as Indian pharma companies.

He has played pivotal role in competency development in medical writing by developing Medical writing training and certification programs.

He has also been ex-chair of DIA India Medical Writing Community.

He has been a visiting faculty at various Clinical Research training institutes and has been a prominent speaker at various Industry Associations, academic institutions, conferences and workshops.

He is happily married to Dr. Nisha and blessed with two lovely daughters.



### Data Anonymization – Boon for Research Advancements

**Dr. Binu V.S. , Assistant Professor of Biostatistics, Department of Biostatistics, National Institute of Mental Health and Neurosciences (NIMHANS), Bengaluru**

Dr. Binu is a Master in Statistics from University of Kerala, Trivandrum, India and obtained Ph.D. from Manipal University for the thesis titled “A study on covariance matrix and its applications in microarray data analysis”.

He has 19 years of research and teaching experience in the field of biostatistics and epidemiology.

He has more than 60 publications in various national & international journals. He is a statistical reviewer for Journal of Advanced Nursing and reviewer for Indian Journal of Medical Research.

He is the first rank holder in University of Kerala for undergraduate statistics examination held in 1996. He has guided more than 45 PG dissertations and currently guiding six Ph.D. scholars. He has conducted more than 50 workshops in research methodology and biostatistics at various institutions across the country. He is the treasurer of International Biometric Society –Indian Region since 2015. His areas of research interest are statistical genetics and microarray data analysis, error analysis, spatial epidemiology, linear models and multivariate methods.