IASCT
Indian Association for Statistics in Clinical Trials

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- Free webinar from PSI
- Time zone: UK

PSI Webinar 232: Risk Based Monitoring & QTL's

Since the introductio of ICH-E6 R2 Addendum sponsors must introduce formal Quality Risk Management and define Quality Tolerance Limits to their clnical development programs. This webinar will cover an introduction to those concepts, recent developments and examples of how companies are defining QTL's in practice.

When 12/2/2020 2:00 PM - 3:30 PM

Where UNITED KINGDOM

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Tim Rolfe,
GlaxoSmithKline

Marcin Macowski,
GlaxoSmithKline

Chris Wells,
Roche Products Ltd

Marta Kozińska,
AstraZeneca

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Speaker	Biography
Tim Rolfe	Tim Rolfe is Director of Central Monitoring & Data Analytics at GlaxoSmithKline & has over 20 years of experience working as a statistician at in the pharmaceutical industry. He has been part of GSKs RBM team since its inception in 2012, providing statistical leadership in the development and implementation of GSK's RBM strategy within clinical trials. Before joining GSK, Tim studied Applied Statistics at Sheffield Hallam University and holds a MSc in Medical Statistics from the University of Leicester in the UK.
Marcin Macowski	Marcin Makowski is the Head of Centralized Monitoring and Data Analytics at GSK. Previously Marcin held similar positions at AstraZeneca and UCB. Last 10 years of Marcin's career was revolving around establishing and improving Risk Based Monitoring models including centralized monitoring and quality tolerance limits. Marcin co-led the group that produced the first TransCelerate recommendations on QTLs in 2017 and is member of the TransCelerate topic team that recently published the expanded QTL framework. Marcin holds MD and PhD degrees from the Warsaw Medical University.
Marta Kozińska	Marta Kozińska is an Associate Director Centralized Monitoring with over 10 years of experience in clinical trials which includes, Data Management, Site Management (CRA), Study Management (Project Manager – Global Study Leader) as well as RBQM implementation and Risk Management. Marta has an MSc Eng in Biotechnology from the Warsaw University of Life Sciences and is a certified PMI Project Manager. For the last 8 years Marta has worked for AstraZeneca, where for 3 years she has been part of Centralized Monitoring Team. During these last 3 years she has been leading multiple projects aiming at e.g. proper implementation of Quality Tolerance Limits, Centralized Statistical Monitoring and improvements in ways of working. Apart from that she represents AstraZeneca in TransCelerate QTL working group.
Chris Wells	Chris Wells is a Senior Statistical Scientist who has a total of 23 years experience in the industry. Chris has an MSc in Medical Statistics from the London School of Hygiene. For the last 11 years Chris has worked for Roche Products Ltd where for 4 years she led the Statistical Monitoring Team which during the past year has also included the application of Quality Tolerance Limits. More recently her work is involving the implementation of Data Surveillance and Advanced Analytics.