	Clinical Data Integration & Management **March 20th** **Program Day One**
07:30	Registration and refreshments
08:15	Chair's opening remarks ***Terry Katz,*** *Director, Head of DM and Statistics,* ***Merck Animal Health***
08:30	**Analyzing which software needs to be utilized to ensure a timely and more automated process** • Emphasizing for fewer data uploads to reach a less manual procedure and quicken your operations • Exploring possibilities to extend standards to cover more complicated data matters to represent semantics in a more uniform and consistent way • Examining a new technical approach on machines for a readable and faster search of terms based on meaning • Keeping up constantly with new terms companies should be using through FDA directions to keep your analysis key points tidy • Aligning your software to the industry standards to keep up with the newest updates in this field and save crucial time ***Kimberly Dorsch, CCRP, CRCP,*** *Senior Manager Global Regulatory and Clinical Affairs,* ***LifeNet Health***
09:00	**Pinpointing integration of data pulled through eSource to boost your trial evaluations accuracy** • Including electronically centralized data sources such as laboratory data to have a solid start • Accepting data from different sources to implement a great quantity of high quality data from non-traditional sources • Studying technology progress to answer compliance questions to ensure your studies never face issues • Exploring eSource implementation to analyze pros and cons about data production quality and quantity • Utilizing your system within timelines to avoid errors and to always use the latest protocol to have immediate access to pertinent data ***Robert Ocken,*** *Business Technology Client Partner – Clinical Data Aggregation and Insights,* ***Pfizer***

09:30	**Sessions reserved for SQN Clinical**
10:00	**Addressing innovative utilization of new tools to achieve a straightforward integration to have all of your data tidily in one place** • Exploring new standardized tools to accomplish quicker re-spacing • Collecting optimal data from patients to achieve perfect data interpretations • Reviewing general data standards and flow to gain easy access to your warehouse for quicker searches • Gathering data from different sources in a timely manner for a timely application of data to your study • Securing correct collection of non central lab data to make sure every needed information is present in your main database ***Rajat Nanda,*** *Portfolio Director,* ***Novartis***
10:30	Morning refreshments and networking
11:00	**Deploying helpful hi-tech solutions to track separated systems and integrating them in one within timeframes** • Recognizing strategies to follow when looking at data to find a way to build a data tracker to examine every data specifically • Programming analyses individually to ensure all of them are based on the relevant study to gather the best information • Creating individual data analysis to comply with certain standards and simplify to have defined conclusions • Gathering your conclusion on the same table to build a report which can give optimal inputs • Combining multiple pieces of information together to make IT landscape straightforward to put information together in a consolidated manner ***Laszlo Vasko,*** *Senior Director, R&D M&A Integration Lead,* ***AstraZeneca***

11:30	**Sessions reserved for eClinical Solutions**
12:00	**Examining ICH's recent e6 (R2) guideline to maintain required standards and run compliant trials** • Appreciating crucial points of this guideline in the data management field to make trials easier for companies • Creating sub teams to discover and implement what it is needed to find solutions in house and save time and money • Highlighting the process of documentation needed by companies to comply with regulations • Exploring what consequence could happen in case of non-compliance to be ready to react • Defining ways to carefully and efficiently check manuals and different committees guidelines ***Barbara Skinn, PhD, RN,*** *Operations Portfolio Lead, Immuno-Oncology,* ***BMS***
12:30	**Presenting end to end continuous data integration in digital clinical trials** ***Eric Hillaert,*** *Senior Director of Product Development, Analytics,* ***EDETEK***
13:00	Lunch and networking
14:00	**Sessions reserved for sponsor**
14:30	**Handling newest European regulations around data protection laws 2016/679 to be absolutely prepared when they will come into force** • Presenting how new regulations enforcements are going to replace past agreements to face new guidelines appropriately • Exploring new ways to comply with global data protection (regulations 2016/679) to deal with the current lack of guidance • Investigating potential data omissions because of the impossibility to use EU data to diminish negative effects on studies based in the USA • Underlining European patients' different rights to obtain reliable results and not to have people leaving your trials • Analyzing EU revival of many GCPs to compliantly implement your available data which must be present on companies' portals ***Terry Katz,*** *Director, Head of DM and Statistics,* ***Merck Animal Health***

15:00	Afternoon refreshments and networking
15:30	Speaker Hosted Roundtables Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best practice and develop solutions to critical challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, roundtables are an exciting, interactive way to build your personal network and learn from the experience and expertise of others. Each roundtable session lasts for 45 minutes, and delegates may attend up to 2 roundtables
Roundtable 1	Analyzing any potential new EDC system for a quicker integration and better study flow ***Shari DeVore,*** *Senior Manager,* ***Sanofi – Data Expert Services***
Roundtable 2	Choosing the right vendor to make sure investments on devices pay off in the shortest time possible ***Terrence O. Tormey,*** *CEO,* ***Kibow Biotech***
Roundtable 3	Sharing best practices for an optimal utilization of data in real time to be able to get to your conclusions more quickly ***Abhijit Parab,*** *Director, Clinical Data Management and Programming,* ***Allergan***
Roundtable 4	***Patrick Zbyszewski,*** *VP, Data Management,* ***Onconova***
17:00	Chair's summary and close of conference

	Clinical Data Integration & Management **March 21st** **Program Day Two**
07:45	Registration and refreshments
08:30	Chair's opening remarks ***Terry Katz,*** *Director, Head of DM and Statistics,* ***Merck Animal Health***
08.45	**APIs are the Future of Clinical Research Data Exchange** • Addressing how the availability of standard application programming interfaces, (APIs) will change how data and metadata are exchanged • Analyzing how APIs foster increased efficiency in clinical research processes • Assessing how APIs can improve data quality • Studying examples highlighting API usage for eSource • Reviewing examples highlighting API use in common data exchange scenarios ***Sam Hume, DSc,*** *Head of Data Exchange Technologies,* ***CDISC***
09:30	**Sessions reserved for Inamed**
10:00	**Conducting clinical trials in Europe in the era of data privacy and anonymization** • According to studies only 6% of pharma companies are prepared for the **General Data Protection Regulation (GDPR)** coming into effect in May 2018 in the European Union. What does this mean for the redaction of patient identifiers? • **Clinical Trial Regulation 536/2014** establishes an EU portal for public access to clinical trial data upon a marketing authorization decision. How can Sponsors prepare data in a traceable and transparent way? • **ICH GCP E6 (R2) addendum** encourages a risk-based approach to data management. How can Sponsors apply this to privacy and transparency? ***Jo Marshall, Director of Statistical Programming / UK Country Manager, CROS NT***
10.30	Morning refreshments and networking

11:00	**Panel: Establishing perfect communication within different departments to improve every step in the clinical operations and data management cooperation** • Establishing pragmatic communication from the beginning to avoid waste of time in data already monitored • Encouraging regular cross function meetings across trials to ensure central study monitoring • Working directly with PV, clinical operations and biostatistics teams to have the right information to analyze • Building relationships and good teamwork through defined team structures to create structured action plans • Ensuring drug approval through open communication and precise questioning to colleagues in different sites ***Jacqueline Gough,*** *Advisor – Clinical Risk Management, Data Sciences and Solutions,* ***Eli Lilly*** ***Dr. Georgia Mitsi,*** *Sr. Director Search & Evaluation, Digital Healthcare Initiatives,* ***Sunovion Pharmaceuticals*** ***Chris Grady,*** *Associate Director, Clinical Data Management.* ***Progenics Pharmaceuticals*** ***Audrey Hill,*** *Senior Director, Data Management,* ***Advaxis***
11:45	**Evaluation of risk identification methods and assessment of potential gaps to ensure RBM success** • Identifying site risk assessment best practices across more than one risk identification tool/system • Investigating whether identified risk or perceived risk is driving monitoring frequency or are other factors involved? • Recognizing and identifying data trends not easily visible during on-site monitoring using centralized data monitoring • Discovering whether real-time trial data access provides earlier risk identification and mitigation ***Caroline Manning,*** *Associate Director, Headquarters Clinical Quality Management,* ***Merck*** ***Rosanne Petros,*** *Associate Director, Clinical Research Manager,* ***Merck Research Lab***
12:15	**Adopting architecture design strategies for an integrated system for clinical trials** • Analyzing real world data to support solutions in the regulations field to increase chances of drug approval • Evaluating ideal data management in the right framework to ensure quick validation of your data • Building a careful review of databases to accurately transfer data to different warehouses • Extracting and transcribing data carefully from the central database to use them to obtain FDA validation • Comparing and doing cross reference data with clear explanations from all of your clinical trials keeping a good balance to avoid FDA guaranty

	Wenle Zhao, PhD, *Professor in Biostatistics****, Medical University of South Carolina***
12:45	Lunch and networking
13:45	**Applying innovations to your site to make your staff work smarter and not harder and accomplish all of your goals** • Developing the ability to make work fully understandable for professionals involved in trials to run your study optimally • Uploading your data onto your website as quickly as possible to comply perfectly with requirements • Ensuring that tools are at service of your trial to avoid acquiring new devices and starting from the beginning again • Having electronic diaries which must be user-friendly to have a patients' demographics as broad as possible • Utilizing appropriate tools to present data meeting population requirements to give reliable results ***Lindsey Mathew,*** *Director, Clinical Operations,* ***Valeant***
14:15	**Sessions reserved for sponsor**
14:45	**Assessing innovative data cut plan** • Unveiling what is a data cut plan • Analyzing prerequisites to do the data cut • Learning how it helps to clean & review the data • Discovering how (often) you need to do it ***Kumar Komuravelli,*** *Director, Clinical Data Management,* ***Mallinckrodt Pharmaceuticals***
15:15	Chair's summary and close of conference ***Terry Katz,*** *Director, Head of DM and Statistics,* ***Merck Animal Health***