## Argus User Group Agenda

**Boston 18-20 October 2017**

### Wednesday October 18

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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| 6:00 – 9:00pm | **Cocktail Reception**  
Kick off AUG Boston by mingling with your peers while enjoying cocktails and an array of appetizers.  
*Apropos Restaurant, Lobby level, Boston Sheraton Hotel* |

### Thursday October 19

**All sessions in the Republic Room**

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<tr>
<th>Time</th>
<th>Session</th>
<th>Event</th>
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| 9:00 – 9:10am | S1-1    | **Welcome**  
*Host: Axel Hagel, Foresight* |
| 9:10 – 9:40am | S1-2    | **Keynote Address**  
Technical, technological and regulatory outcomes of Web-RADR  
Recognizing Adverse Drug Reactions using robotics process automation (RPA), AI, social media dashboard, Apps and signals. What do these mean for operational PV?  
*Speaker: Dr. David J. Lewis, Novartis* |
| 9:40 – 10:40am| S1-3    | **What’s New in Argus 8.1.1**  
Argus and Argus-J  
Regulatory background and release approach & roadmap  
Major enhancements and bug fixes  
*Speaker: Axel Hagel, Foresight* |
| 10:40 – 11:00am|        | **Coffee Break** |
| 11:00 – 12:00pm| S1-4   | **Oracle Suite Update**  
Update of the Argus Suite Release Roadmap  
*Speaker: Industry, Oracle* |
| 12:00 – 1:00pm|        | **Lunch**  
*Location: Back Bay Ballroom D* |
| 1:00 – 1:50pm | S1-5    | **MedDRA Up-Versioning of Argus PV Data: Best Practices**  
Pragmatic workflows and best practices for implementing new versions of the MedDRA dictionary and up-versioning coded data in Argus Safety.  
*Speaker: Brian K. Perry, BKP Technologies* |
| 1:50 – 2:50pm | S1-6    | **Implementation of E2b R3 in Argus 8.x- Points to Consider**  
*Speaker: Uwe Trinks, Foresight* |
| 2:50 – 3:10pm |        | **Coffee Break** |
| 3:10 – 4:10pm | S1-7    | **Case Intake**  
Innovative Solutions to Streamline Case Intake in PV  
*Speaker: Scott Fonseca, Foresight* |
| 4:10 – 5:00pm | S1-8    | **Are you ready for November 8 and 22?**  
There are many changes coming for EMA and NCA reporting post November 22nd. Are you ready for the transition as well as the interim reporting requirements during the cut-over phase from Nov 8 through Nov 21?  
*Speaker: Uwe Trinks & Panel* |
| 6:30 – 9:30pm |        | **Dinner Event**  
Experience a Boston favorite! Enjoy cocktails in a 1920's style speakeasy followed by a New England inspired dinner menu.  
*Carrie Nation Restaurant & Cocktail Club* |
## Friday October 20

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<thead>
<tr>
<th>Time</th>
<th>Track A</th>
<th>Track B</th>
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<tbody>
<tr>
<td>9:00 – 10:45am</td>
<td>Ask the Experts&lt;br&gt;Questions submitted by attendees&lt;br&gt;Audience discussions&lt;br&gt;&lt;br&gt;<em>Panel: Uwe Trinks, Axel Hagel and Saurabh Khurana, Foresight Group</em></td>
<td>Track B: Back Bay Ballroom D</td>
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<td>10:45 – 11:00am</td>
<td>Coffee Break</td>
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<td>11:00 – 12:00pm</td>
<td>Artificial Intelligence in AE Detection&lt;br&gt;Moving towards automatic recognition of adverse events within any large amount of unstructured data.&lt;br&gt;&lt;br&gt;<em>Speaker: Siva Nadarajah, QuintilesIMS</em></td>
<td>Access to EudraVigilance by MAHs&lt;br&gt;Overview of the EVDAS functionalities and access to EudraVigilance by MAHs to comply with their PV obligations&lt;br&gt;&lt;br&gt;<em>Speaker: Uwe Trinks, Foresight</em></td>
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<td>12:00 – 1:00pm</td>
<td>Lunch</td>
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<td>1:00 – 1:45pm</td>
<td>The renaissance of patient reporting - and the use of technology&lt;br&gt;Patient-reported safety outcomes are back - but did they ever go away?&lt;br&gt;&lt;br&gt;<em>Speaker: Dr. David J Lewis, Novartis</em></td>
<td>Do small companies need to upgrade?&lt;br&gt;• Why do it?&lt;br&gt;• What is the right time?&lt;br&gt;• What is involved?&lt;br&gt;• How will it impact my business?&lt;br&gt;&lt;br&gt;<em>Speaker: Updesh Dosanjh</em></td>
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<td>1:45 – 2:45pm</td>
<td>Argus Functionalities&lt;br&gt;Did you know it could do this...? Hidden functionalities within Argus that you may not have been aware of&lt;br&gt;&lt;br&gt;<em>Speakers: Axel Hagel and Saurabh Khurana, Foresight</em></td>
<td>How mature is your PV process?&lt;br&gt;Industry benchmarking survey results and practical tips to improve your process&lt;br&gt;&lt;br&gt;<em>Speaker: Mark Loudon, Foresight</em></td>
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<td>2:45 – 3:00pm</td>
<td>Coffee Break</td>
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<td>3:00 – 4:00pm</td>
<td>Productivity Tools&lt;br&gt;Taking Auto-Narratives and Duplicate Searching in Argus to the next level. Obtain submission-ready narratives with natural language formation and simplify the duplicate searching a ranked result set.&lt;br&gt;&lt;br&gt;<em>Speaker: Axel Hagel, Foresight</em></td>
<td>Building a new Business Process due to an Argus implementation&lt;br&gt;&lt;br&gt;<em>Speaker: Julie Ouzilou, Sanofi</em></td>
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<td>4:00 – 4:50pm</td>
<td>Panel Discussion IDMP&lt;br&gt;Overview of IDMP and the challenges ahead. How is industry preparing for IDMP?&lt;br&gt;&lt;br&gt;<em>Panel: Industry / facilitated by Uwe Trinks, Foresight</em></td>
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<td>4:50 – 5:00pm</td>
<td>Closing Remarks</td>
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Foresight Group

**Mr. Updesh Dosanjh** is the European head of Foresight, with over 25 years of knowledge and experience in the management, development, implementation, and operation of processes and systems within the life sciences industry as well as other industries. He has worked in the Drug Safety area for over 10 years.

He has designed and managed projects across all sizes of clients across all major geographies.

Prior to joining Foresight, Mr. Dosanjh was a Senior Managing Consultant for WCI and worked for Logistics Consulting Partners, Amersys Systems Limited and FJ Systems.

Mr. Dosanjh earned a Bachelor’s degree in Materials Science from Manchester University and a Master’s degree in Advanced Manufacturing Systems and Technology from Liverpool University.

Foresight Group

**Mr. Scott Fonseca** is a Vice President and the Global Head of Worldwide Sales and has over 20 years of experience within the life sciences industry.

Prior to Foresight Mr. Fonseca spent 13 years at Phase Forward where he was the Global Sales Director of safety and data warehousing portfolio, which included safety system applications, signal detection, and analytics. During his tenure, he also was the global sales lead on strategic enterprise accounts selling both safety and clinical software and services. He has held Enterprise Sales roles at Oracle and was the North American Sales Director at MyMeds&Me selling direct capture Patient and Health Care Professional solutions.

Mr. Fonseca received his Bachelor of Science degree in Electrical Engineering Technology from the University of Massachusetts.

Foresight Group

**Mr. Axel Hagel** has over 21 years of experience in the life sciences industry, specializing in the deployment of drug safety applications in North America, Europe, and Japan. He has unique experience and implementation skills for the Argus Safety Suite, including Argus J, and is recognized in the drug safety sector as a Pharmacovigilance industry leader. Prior to Foresight, Mr. Hagel served as the North American Practice Partner at Deloitte, and as Vice President of Drug Safety at Relsys International, Inc., the developer of Argus Safety Suite before its acquisition by Oracle. Mr. Hagel completed his Bachelor of Computer Science with High Honors at Carleton University in Ottawa, Canada.
Foresight Group

Mr. Saurabh Khurana is a Partner at Foresight based in Noida, India, with over 11 years of experience in drug safety. Mr. Khurana specializes in the development, implementation, integration, and operation of systems within the drug safety industry. He has unique experience and implementation skills for the Argus Safety Suite, including Argus J, and has done extensive work on very large data migrations from Global and Japanese data sources.

Prior to Foresight, Mr. Khurana worked at Relsys India and United States as an Application Architect. He led the product architecture of Argus Safety 4.2+ and 5.x product versions.

Mr. Khurana holds Bachelor of Technology and Master of Technology degrees in Computer Science from the Indian Institute of Technology in New Delhi.

Novartis Global Drug Development

Dr. David Lewis joined Novartis in March 2007 following 20 years' pharmacovigilance at GSK and at Shire Pharmaceuticals. He was appointed EU QPPV at Novartis Pharma AG from April 200, then moved to Global Head of Pharmacovigilance Systems and Data Management, followed by Global Head of Pharmacovigilance in February 2011. He was confirmed as Global Head of Pharmacovigilance (including vigilance for medical devices) for Novartis Patient Safety in June 2016, then moved to Senior Adviser in September 2017. Dr. Lewis has worked in country affiliates and in a variety of global safety and risk management functions with both investigational and marketed products, as well as in roles concerned with systems and processes. Dr. Lewis is the author of papers on the safety of medicines as well as research papers on neuropharmacology. He has a number of academic links, including being named Visiting Senior Fellow, Faculty of Health and Human Sciences, University of Hertfordshire. Dr. Lewis is Project Coordinator for the WEB-RADR consortium.

Outside of work, Dave runs a smallholding and maintains an interest in retaining his advanced driving license. He actively participates in various sports, having played cricket and hockey at county and national level respectively. He maintains that he will retire from competitive cricket when either of his sons, aged 24 and 26, ends the season with a higher batting average and having taken more wickets and catches!
Foresight Group

Mr. Mark Loudon has worked with life-science systems in clinical, regulatory and pharmacovigilance for nearly thirty years, both in Europe and in the U.S. working for pharma and software companies in the industry. He has been involved in the creation and design of safety and risk management software, and involved in standardization of safety business processes across multiple companies. With a compliance and regulatory focus, Mark works with customers to create practical ways of addressing compliance and safety needs in case processing and analytics.

QuintilesIMS

Mr. Siva Nadarajah was founder and CEO of Semantelli, a healthcare focused social media analytics and compliance start-up that was acquired by QuintilesIMS. He currently serves as the Global General Manager for big-data and compliance at QuintilesIMS. Siva is also an early stage investor and adviser for various tech start-ups.

Siva was recognized for uncovering two major internet security holes in the early days of internet, which forever changed how people accessed secured sites from public computers. Siva owns a US Patent on “Multidimensional profiling of Healthcare professionals” and was recently invited by New England Patriots owner Robert Kraft’s Precision Medicine Initiative to speak at Harvard Business School about the impact of "Fake Health News" on US healthcare system.

BKP Technologies

Mr. Brian K. Perry is the founder, President and CEO at BKP Technologies, Inc. of Newton, MA. He has 27 years of experience in life sciences, 23 years in pharmacovigilance systems, and 18 years of experience with the Argus Safety suite. He provides professional consulting services and software products in the areas of MedDRA Coding Tools; Pharmacovigilance and Clinical Data Management Systems; Computer Systems Validation; and Software Application Design and Development.

Prior to starting BKP Technologies in 2001, Brian was the former President and CEO of Versal Technologies, Inc. of Boston, MA, delivering IT solutions to major pharmaceutical clients around the world. Prior to starting Versal in 1995, Mr. Perry was the Director of Information Systems at Vertex Pharmaceuticals.
Foresight Group

Dr. Uwe Trinks, Director, and Argus and Drug Safety SME, has over 30 years of life sciences experience. Prior to joining Foresight Group, he served as the CIO of Sentrx where he led hosting and managed services for over 25 Argus safety database instances for 10 years. Previously, he served as the Executive Director and Head of Research Information Management for Novartis. Dr. Trinks earned a M.S., Major: Organic Chemistry and Natural Products Chemistry, from Federal Institute of Technology in Zurich, Switzerland and a Ph.D. Organic Chemistry from Federal Institute of Technology. He has also completed Postdoctoral Research in Biochemistry at Stanford University.