



Healthcare 
Working Group

6th Annual Systems Engineering in Healthcare Conference

Minneapolis/Saint Paul

April 28-30, 2020

<https://www.incose.org/hwg-conference>

The INCOSE Conference on Systems Engineering in Healthcare enables participants to share the best practices in the latest Systems Engineering topics as applied to both Medical Devices and Healthcare Delivery.

The theme for the conference is

Advancing the Practice of Systems Engineering in the
Healthcare Industry

Conference Tentative Program- Healthcare Conference Tutorial Day (April 28th)

Tutorials 28-Apr				
	Ballrom 1	Ballroom 2	Ballroom 3	Ballroom 4
7:00	Breakfast - Mezz Lobby			
8:00	Tutorial	Tutorial	Tutorial	Tutorial
8:30	Break			
10:00	Tutorial	Tutorial	Tutorial	Tutorial
10:30	Lunch			
12:00	Tutorial	Tutorial	Tutorial	Tutorial
13:00	Break			
	Tutorial	Tutorial	Tutorial	Tutorial

Healthcare Conference Day 1 (April 29th)

29-Apr				
	Ballroom 1	Ballroom 2	Ballroom 3	Ballroom 4
7:00	Breakfast - Ballroom Lobby			
8:00	Introductions			
8:30	Keynote: Shawn Kroll			
10:00	Break / Networking			
10:30	Healthcare Delivery	QA/Compliance/ Safety	MBSE	Tools Vendor Day
12:00	Lunch			
13:00	Healthcare Delivery	Agile and Lean Methods	MBSE	Tools Vendor Day
14:00	Break			
14:15	Sponsor Presentations			
15:15	Break / Networking			
15:45	Healthcare Delivery	Agile and Lean Methods	MBSE	Tools Vendor Day
17:15	Day Adjourns			
17:30	JAMA Reception / Happy Hour			
19:00	Banquet			

Healthcare Conference Day 2 (April 30th)

30-Apr				
	Ballroom 1	Ballroom 2	Ballroom 3	Ballroom 4
7:00	Breakfast - Ballroom Lobby			
8:00	Keynote: Michael Pennock			
9:30	Break / Networking			
10:00	Healthcare Delivery	Machine Learning / AI / Digital	SE Tools	Tools Vendor Day
12:00	Lunch			
13:00	Healthcare Delivery	Machine Learning / AI / Digital	SE Skills	Tools Vendor Day
15:00	Break / Networking			
16:00	Confereent Retrospective			
	Conference Adjourns			

Keynotes



Keynote: Speaker: Shawn Kroll, Vice President of Robotics Development at Stryker

“The strategic value of Systems Engineering to a Technology Organization”

Abstract

In a world of technical, regulatory, legal and financial complexity it is hard to imagine life without a culture of Systems Engineering. From the medical technology perspective, we must not only innovate to improve surgical outcomes, we must do so while maintaining a keen focus on healthcare economics, especially in the era of Accountable Care. But how does Systems Engineering impact those variables synergistically? Perhaps more importantly, how do we sell the long-term value of the investment in SE? As Engineers, we often focus on technical value, but if we think that SE is about V-diagrams and requirements structure, we have completely missed the point! Sure, those are key components of the process, but Executives cannot place value on Engineering discipline alone, nor do they have the time to truly grasp and understand it. The real story is about achieving quality while building in modularity, scalability and reusability and building a Product Development pipeline on a strong foundation. The list of practices and disciplines that “company X” must have...that they cannot live without goes on and on. Books, courses, conferences and careers have been built on this very list, but if the value is not demonstrable or able to be articulated in an elevator pitch, the entire list isn’t worth the paper it was written on and like all unnecessary costs - it will be the first thing to go!

Bio Summary

Shawn M. Kroll, Vice President of Robotics Development, started his career with Stryker Corporation 18 years ago as a Manufacturing Support Staff Engineer where he oversaw critical processes for hip arthroplasty prosthetic implant manufacturing such as; hydroxylapatite synthesis and robotic thermal coating applications and over the next 15 years he came full circle from working with robots that helped him to developing robots that help patients and surgeons! Throughout his tenure, Shawn has held numerous roles of increasing responsibility within Stryker’s Joint Replacement business, including several Leadership roles in Product Development, Global Commercial Marketing and Portfolio Strategy across the Hip, Knee and Upper Extremity segments. Throughout his tenure he led his teams in the development and launch of numerous key products for Stryker, some of which are still power brands for the company today such as; Restoration Modular, Trident, X3 and the Dual Mobility offering. He also holds 4 US patents for innovative instrumentation concepts developed during his work in leading the revitalization of Stryker’s Upper Extremity reconstructive business. Shawn led the Marketing efforts during the integration of Mako Surgical, a pivotal acquisition for Stryker 6 years ago and now leads the Product Development function where he oversees a diverse global organization that is dedicated to developing best-in-class surgical robotics technologies.



Keynote Speaker: Michael Pennock, PhD, Assistant Professor, School of Systems and Enterprises, Stevens Institute of Technology

“Solving the wrong problem: Lessons learned from applying systems simulation approaches to the adoption of Evidence-Based Interventions (EBI)”

Abstract

Evidence-based interventions (EBIs) have been slow to translate into clinical practice. It has been estimated to take an average of 17 years to translate the results of an RCT into real world settings. Healthcare providers are often skeptical of evidence from RCTs because of perceptions that RCTs are performed under idealized circumstances, raising concerns that differences in context or patient demographics could erase the beneficial impact seen in the effect sizes. While some skepticism may be justified, the resulting risk aversion sets a high bar for the acceptance and use of EBIs. It was hypothesized that a class of system simulation called a policy flight simulator could help to overcome this skepticism because it would enable healthcare providers to see impacts of EBI implementation on their particular organizations. To find out, researchers from the Stevens Institute of Technology, the University of Pennsylvania School of Nursing, and the Wharton School collaborated to develop and evaluate a simulation of the adoption of an EBI called the Transitional Care Model (TCM). The resulting simulation was reviewed by multiple payer and provider organizations. What was found is that, while the organizations felt the simulation was useful, it was really fundamental structural issues with the US healthcare system that inhibited adoption. These issues included the fragmented nature of the system, disincentives resulting from the payment system, and policies instituted by the Centers for Medicare & Medicaid Services. Ultimately, the simulation development effort was solving the wrong problem, but the study still yielded useful insights regarding the development and application of systems simulation approaches to healthcare operations and policy.

Bio Summary

Michael Pennock is an Assistant Professor in the School of Systems and Enterprises at the Stevens Institute of Technology. The long-term goal of his research is to create new approaches to design and evolve large-scale systems that consist of interacting engineered and social components. The increasing interconnectivity of modern systems ranging from transportation systems to healthcare delivery systems to app ecosystems has rendered many traditional approaches to systems engineering inadequate. Central to resolving this dilemma is the development of techniques to computationally model these systems in a way that is useful for engineers. Understanding how to construct and use these types of computational models, with a particular emphasis on integrating human and social factors, has been the central focus of his research.

Michael has been PI or Co-PI on multiple sponsored research projects including sponsors such as the US Department of Defense and the Robert Wood Johnson Foundation. Recent projects include employing machine learning techniques to identify modularity violations in cyber-physical systems, adapting graphical analysis methods to understand the composability of computational models, using simulation to understand the adoption of evidence based interventions in the US healthcare system, and analyzing policies to deter counterfeit electronic parts in supply chains. Results from this research have been directly integrated into the courses he teaches in the areas of statistics, operations research, and decision analysis.

Michael has also worked as a senior systems engineer in various lead technical roles for the Northrop Grumman Corporation. He holds a Ph.D. in Industrial Engineering from the Georgia Institute of Technology and Bachelor's and Master's degrees in Systems Engineering from the University of Virginia.

Invited Talks

Experience Report: Agile development of Software as a Medical Device Applications for Pharma - Eli Snell

Track: Agile

I'll describe the journey and challenges of adapting the software development life cycle processes at Roche for the new digital health solutions organization, a new group acting as a startup within the Diganostics unit of Roche. We're developing digital health applications, primarily mobile applications, with software as a medical device components for pharmaceutical patients and HCPs.

Human factors approval of medical devices - key steps along the submission path - Jeff Horvath

Track: Healthcare Delivery

Human factors validation is a key component of getting your product approved by the FDA. In this talk, I'll talk through some of the key steps along the way and share some lessons learned and tips that may help navigate the sometimes confusing and scary journey. I'll touch on various topics such as design documentation, risk analysis, scheduling, communicating with the FDA, and reporting results. The goal is to demystify the process and help increase your likelihood of having your submission (plans and reports) accepted by the FDA without the need for costly and time-consuming rework.

Enhancing Health Through Machine Learning - Erkin Otles

Track: Healthcare Delivery

"Water, water everywhere, Nor any drop to drink."

The entire healthcare industry is drowning in data, yet there are few ways that data are used to support patients achieve optimal health. Machine Learning and Artificial Intelligence are techniques that promise to convert raw data into actionable insight. This talk will discuss the fundamentals of these techniques and explore their potential contributions to health and healthcare.

The Systems Engineer as Translator (Tutorial) - Zane Scott

Track: Healthcare Delivery

The major challenge facing the systems engineer seeking to bring to bear the power and leverage of systems engineering in the healthcare delivery domain is that of translation. All disciplines and specialties have their own language and ways of communicating. Successful movement in two or more such domains at once requires those transiting the professional borders to be fluent in the languages used in each of the domains. Of particular concern are the areas of overlap where similar or the same concepts must be used in multiple areas.

Too often this challenge is confronted by the insistence of one domain's practitioners that those in other areas learn and use the terminology and usage conventions of their domain in all overlapping work. Particularly where the professionals from one discipline are called in to "help" practitioner's in another, the "helpers" will bring and dispense the language in which they are accustomed to working and expect the "helped" to learn to communicate in new and unfamiliar ways in order to access the benefit of the "help."

Nowhere is this difference in language and context more markedly delineated than in the world's of systems engineering and healthcare delivery. Practitioners in each of those areas speak a language replete with specialized terms and usage conventions. These have little or no overlap. The opportunity for miscommunication and confusion are numerous.

But systems engineering success demands that its practitioners learn to speak the language of the working context. In this way they can accurately learn and appreciate the problems to be addressed and convey to their "customers" the nature and power of systems engineering solutions in ways that the customers can understand and act on.

Medical Device Interoperability Reference Architecture (MDIRA) – Daniel O'Neil

Track: Healthcare Delivery

Objectives:

- Advance MDI to improve patient safety through standardization of healthcare delivery
- Identify a collaborative Federal/industry approach in pursuing answers to the questions
- Conduct multiagency/multi partner collaborative research to develop a sustainable framework of autonomous /closed loop prototypes for military health care which are dual use for the civilian healthcare system

What the MDI Reference Architecture Can Provide

- Specifies an environment into which combinations of medical devices, some under closed-loop control, can be quickly integrated to meet immediate trauma care needs
- Provides a common terminology and taxonomy for physical and functional elements
- Identifies operational interfaces and operational support assumptions
- Identifies the pertinent interoperability standards as well as requirements (e. g. for medical devices) not yet addressed in the standards (stimulates enhancements to standards)
- Supports development of Reference Implementations of core components
- Enables an open-systems business model

A Trade Study Framework for System Architecture Selection – Matthew Johnson

Track: Machine Learning / AI

When defining a high-level system architecture to satisfy various stakeholder needs, a trade study can be used to assess architecture alternative responses across multiple competing objectives (e.g., usability, performance, affordability, etc.) and provides a deterministic method to optimize and select an architecture. This presentation discusses a framework for conducting such a trade study, including (1) structuring the trade study, (2) analyzing the data, and (3) optimizing the trade space.

Tutorials (April 28th)

Introduction to Systems Engineering – Dave Walden

INCOSE defines systems engineering as an interdisciplinary approach and means to enable the realization of successful systems. It has become an essential discipline to ensure the system of interest is the right solution to meet the stakeholder needs, while being affordable across the life cycle of the system. Systems engineering considers both the business and the technical needs of all stakeholders with the goal of providing a quality product that meets those needs.

The objective of this one-day tutorial is to provide a top-level overview of the discipline of systems engineering and how it can be used to plan, manage, and realize complex systems within the context of demanding business constraints. Participants are introduced to key systems engineering terminology, concepts, and principles in the handbook, answering questions such as:

- What is systems engineering and why is it important?
- What are the key systems engineering concepts and approaches?
- How can you use systems engineering to make a difference on your projects?

Practical information and tools are provided that will help the participants deal with issues that inevitably occur in the real world. The participants will complete several team-based exercises to solidify the concepts being presented. Each student will receive a complete set of lecture notes and an annotated bibliography.

Introduction to Agile Development for Systems Engineering – Kelly Weyrauch

Systems Engineering methods help us produce complex systems. Agile methods help us produce them faster and better. Both together? Awesome. In this tutorial, we will explore principles of Systems Engineering from INCOSE and ISO 15288 System Life Cycle Processes, and the principles of Agile scaling methods such as those defined in the Scaled Agile Framework (SAFe®). Topics to cover include:

- Introduction to Agile Principles and Practices
- Lean and Agile Principles Applied to Systems Development
- Barriers and Benefits to Adopting Agile
- Architecture of Agile Teams, and the roles of Systems Engineering
- Defining Systems
- Delivering Systems
- Verifying and Validating Systems
- Tailoring Agile Software Practices for Hardware and Systems

This Tutorial will be a mixture of slide presentation, large group discussion, and small-group discussions.

Applied Systems Modeling Workshop – Using Capella/Arcadia, an MBSE tool/method (Morning half day) – Stephane Lacrampe and Vijay Thukral

There are many MBSE tools providing powerful modeling capabilities. Graphical representation and management of various systems views, while essential, is secondary to the underlying need for rigorous application of SE principles to perform needs analysis, concept exploration, concept definition, to product design, integration, and deployment.

Among the open-source, Capella/Arcadia is one of the leading MBSE tools on the market. Capella provides practitioners of SE to do product development guided by SE principles that can be easily aligned with your organizations SE approach and incorporation of organization's best modeling practices

The Applied Systems Modeling Workshop highlights Capella/Arcadia, a SE method entrenched-tool with rich modeling environment to explore Capella using the enteral infusion pump model

- Introduce Arcadia method and navigate Capella workflow
- Hands-on workshop to model the enteral infusion pump system. Starting from an existing model we will step through the ARCADIA process: Operational Analysis (OA), System

Requirement Analysis (SA) and Logical Architecture (LA) to build the model with a new feature.

- Perform operational analysis (OA) and add new user's needs and operational capability
- Transition the operational need to System Requirement Analysis (SA) and articulation of new system requirements.
- Perform logical structuring and functional allocation that addresses the new need.

Who should attend? System engineers, system modelers, program managers

Note: Participants are required to have Capella installed on their laptops prior to the workshop. Installation instructions for Capella software will be mailed separately to the participants.

The workshop utilizes the development of an enteral infusion pump to learn (i) the ARCADIA method and (ii) to work with the existing enteral infusion pump model using Capella/Arcadia modeling environment.

Tutorial on Safety and Reliability (FMEA) Analysis with SysML and Cameo Systems Modeler (Afternoon half day) – Saulius Pavalkis and Ronald Kratzke

In this hands-on tutorial we will overview recent OMG standard integrating safety and reliability analysis into MBSE. We will go through motivation and history, current status of the specification and implementation. Second part will be dedicated for hands-on application using model-based FMEA.

For the tutorial you will need installation of Cameo Systems Modeler v19.0 (preferable SP3) with installed Safety and Reliability plugin. Installation files and licenses will be provided before and during tutorial.

After this tutorial participants will:

1. Be familiar with new OMG standard integrating safety and reliability analysis into MBSE.
2. Try and learn safety and reliability implementation integrated to SE language (SysML) and modeling tool (Cameo Systems Modeler).

CSEP/ASEP Exam Tutorial – Steve Zielinski

This single day, in-person tutorial will launch your CSEP/ASEP exam preparation on an efficient path to success. It will be paired with an additional 4, follow-up sessions held online.

Experience with CSEP/ASEP candidates has shown there are two major hurdles to achieving this career distinction: starting and finishing. Candidates are reluctant to start because they feel overwhelmed by the amount of material and uncertain about the depth of knowledge needed to obtain a passing score. Those candidates who do get started, and even put a significant amount of study time in, too frequently avoid the final step of scheduling and taking the exam. This tutorial will help you overcome both obstacles.

You will end the day confident in your ability to pass the exam and with the study tools you need for success. The study tools include:

- Access to a set of practice quizzes. The quizzes are organized by chapter and comprehensive so that you can confidently tune your studying.
- The CSEP Study Guide
- A set of drag-and-drop tools to help your memorization.
- Four follow-up sessions to motivate your progress and answer your questions.

Tentative presentation ordered by track and presentation date.

Authors	Kelly Weyrauch Agile Quality Systems, LLC
Title	Introduction to Agile Development for Systems Engineering
Session	Type: Tutorial Track: Agile & Lean Methods Time: Tuesday, April 28, 2020 Room: Ballroom1

Authors	Eli Snell Roche
Title	Experience Report: Agile development of Software as a Medical Device Applications for Pharma
Session	Type: Invited Track: Agile & Lean Methods Time: Wednesday, April 29, 2020 Room: Ballroom2

Authors	Michael Pafford INCOSE Chesapeake Chapter
Title	Lean Startup Method (LSM) and Agile for Resilient Hospital Reference Model (RHRM) Initial Project Planning (IPP)
Session	Type: Submitted Track: Agile & Lean Methods Time: Wednesday, April 29, 2020 Room: Ballroom2

Authors	Kelly Weyrauch Agile Quality Systems, LLC
Title	The Role of the Systems Engineer in Agile Development
Session	Type: Submitted Track: Agile & Lean Methods Time: Wednesday, April 29, 2020 Room: Ballroom2

Authors	Stephen Speicher and Bohdan Oppenheim Loyola Marymount University
Title	Integration of care for AYA (adolescents and young adults) with cancer

Session	Type: Invited Track: Healthcare Delivery Time: Wednesday, April 29, 2020 Room: Ballroom1
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Authors	George Grant DoD
Title	The Impact of Human Factors Engineering, Systems Engineering, and Information/Communications Technology in Healthcare
Session	Type: Invited Track: Healthcare Delivery Time: Wednesday, April 29, 2020 Room: Ballroom1

Authors	Daniel O'Neil Johns Hopkins Applied Physics Lab
Title	Medical Device Interoperability Reference Architecture (MDIRA)
Session	Type: Invited Track: Healthcare Delivery Time: Wednesday, April 29, 2020 Room: Ballroom1

Authors	Michael Pennock Stevens Institute of Technology
Title	Solving the wrong problem: Lessons learned from applying systems simulation approaches to the adoption of Evidence-Based Interventions (EBIs)
Session	Type: Invited Track: Healthcare Delivery Time: Thursday, April 30, 2020 Room: ALL

Authors	Zane Scott Vitech Corporation
Title	The Systems Engineer as Translator
Session	Type: Invited Track: Healthcare Delivery Time: Thursday, April 30, 2020 Room: Ballroom1

Authors	Eric Kersten bb7
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Title	How to utilize systems perspective to deconstruct problems and avoid medical device design pitfalls
Session	Type: Submitted Track: Healthcare Delivery Time: Thursday, April 30, 2020 Room: Ballroom1

Authors	Erkin Otles University of Michigan
Title	Enhancing Health Through Machine Learning
Session	Type: Invited Track: Healthcare Delivery AND Machine Learning / Digital Time: Wednesday, April 29, 2020 Room: Ballroom1

Authors	Jeff Horvath Balanced Experience
Title	Human factors approval of medical devices - key steps along the submission path
Session	Type: Invited Track: Healthcare Delivery AND Quality Assurance / Compliance / Safety Time: Wednesday, April 29, 2020 Room: Ballroom1

Authors	Naeem Hashmi Boston Scientific
Title	Embedding "Privacy by Design" when Engineering AI/ML powered Digital Health Solutions.
Session	Type: Invited Track: Machine Learning / Digital Time: Thursday, April 30, 2020 Room: Ballroom3

Authors	Eric Wespi Boston Scientific
Title	Failures in Manufacturing AI Implementations
Session	Type: Invited Track: Machine Learning / Digital Time: Thursday, April 30, 2020 Room: Ballroom3

Authors	Brian Baker vRad
Title	Radiology AI: Data and Model Governance
Session	Type: Invited Track: Machine Learning / Digital Time: Thursday, April 30, 2020 Room: Ballroom3

Authors	Mike Celentano and Sharath Gopal Eli Lilly and Company
Title	An Approach to Integrating Systems & Engineering Models for Medical Devices
Session	Type: Submitted Track: Modelling and Simulation Time: Wednesday, April 29, 2020 Room: Ballroom3

Authors	Rainer Dronzek AnyLogic North America
Title	Simulation Modeling of Healthcare Systems
Session	Type: Submitted Track: Modelling and Simulation Time: Wednesday, April 29, 2020 Room: Ballroom3

Authors	Saulius Pavalkis and Ronald Kratzke Catia No Magic, Inc.
Title	Overview of Safety and Reliability (FMEA) Analysis with SysML and Cameo Systems Modeler
Session	Type: Invited Track: Modelling and Simulation Time: Wednesday, April 29, 2020 Room: Ballroom3

Authors	Dave Hoadley, Rick Boldt and Kirthi Devleker MathWorks
Title	BRIDGING THE SYSTEM ENGINEERING & MODEL-BASED DESIGN GULF
Session	Type: Submitted Track: Modelling and Simulation Time: Wednesday, April 29, 2020 Room: Ballroom3

Authors	Christopher Scully US Food and Drug Administration
Title	Modeling the patient as part of physiologic closed-loop control system simulations
Session	Type: Submitted Track: Modelling and Simulation Time: Wednesday, April 29, 2020 Room: Ballroom3

Authors	Saulius Pavalkis and Ronald Kratzke Catia No Magic, Inc.
Title	Tutorial on Safety and Reliability (FMEA) Analysis with SysML and Cameo Systems Modeler
Session	Type: Tutorial Track: Modelling and Simulation AND SE Tools Best Practices Time: Tuesday, April 28, 2020 Room: Ballroom3

Authors	Stephane Lacrampe and Vijay Thukral Obeo Canada / SyEntive Group
Title	Applied Systems Modeling Workshop - Using Capella/Arcadia, an MBSE tool/method
Session	Type: Tutorial Track: Modelling and Simulation and SE Tools Best Practices Time: Tuesday, April 28, 2020 Room: Ballroom3

Authors	Alejandro Ojeda Saint-Martin Smiths Medical
Title	Design validation of medical devices: From a regulatory requirement to a competitive advantage
Session	Type: Submitted Track: Quality Assurance / Compliance / Safety Time: Wednesday, April 29, 2020 Room: Ballroom2

Authors	Patrick Wegerson Patrick Wegerson Consulting
Title	Systematic Medical Device Quality Improvements from the FDA
Session	Type: Submitted Track: Quality Assurance / Compliance / Safety

	Time: Thursday, April 30, 2020 Room: Ballroom2
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Authors	David Walden Sysnovation, LLC
Title	Introduction to Systems Engineering
Session	Type: Tutorial Track: SE Skills Development Time: Tuesday, April 28, 2020 Room: Ballroom2

Authors	Steve Zielinski Boston Scientific
Title	CSEP/ASEP Exam Tutorial
Session	Type: Tutorial Track: SE Skills Development Time: Tuesday, April 28, 2020 Room: Ballroom4

Authors	Shawn Kroll Stryker Medical
Title	The strategic value of Systems Engineering to a Technology Organization
Session	Type: Invited Track: SE Skills Development Time: Wednesday, April 29, 2020 Room: ALL

Authors	Mohamed Ali Hamadeh General Electric
Title	System and Sub-System Requirements Re-Architecting to Achieve Simplification and Architectural Alignment
Session	Type: Submitted Track: SE Skills Development Time: Wednesday, April 29, 2020 Room: Ballroom2

Authors	David Quimby Innovation Radiation
Title	Driving Product Value with Systematic Innovation

Session	Type: Submitted Track: SE Skills Development Time: Thursday, April 30, 2020 Room: Ballroom2
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Authors	Sean McCoy and Francesco Dazzi Trane Technologies / Cherenkov Telescope Array Observatory
Title	Building Trust - A Systems Engineer's Most Powerful Tool
Session	Type: Submitted Track: SE Skills Development Time: Thursday, April 30, 2020 Room: Ballroom2

Authors	Matthew Johnson Boston Scientific
Title	A Trade Study Framework for System Architecture Selection
Session	Type: Invited Track: SE Tools Best Practices Time: Thursday, April 30, 2020 Room: Ballroom2