Global Engage is pleased to announce the Digital Pathology Congress USA, which will be held on June 22-23, 2015 in San Diego, USA at the Town and Country Hotel and Resort. The conference is part of their successful Drug Discovery series which includes events on precision medicine, synthetic biology, the human microbiome and digital PCR as well as being a sister event to their successful European Digital Pathology Congress which attracted over 260 people and 25+ exhibitor companies and the Asian Congress which is scheduled to take place in Malaysia in September 2015.

http://www.globalengage.co.uk/events/

The continuing growth and advances in digital pathology solutions is transforming the industry. With wide ranging applications and benefits including reduction in lab costs, increased workflow efficiency, greater interconnectivity, effective training / education methods, improved decision making is enabling enhanced patient care. The result is that Digital Pathology is rapidly gaining momentum worldwide.

Attracting over 175 industry & academic experts working in all areas of Pathology this two day interactive meeting will provide the opportunity to take home cutting edge strategies, analysis techniques, case study examples and methods to allow you to fully understand both the technology and accompanying informatics and image analysis tools and utilize digital pathology to its greatest potential.

This will be achieved through a vibrant exhibition room full of technology providers showcasing their technologies and other solutions, networking breaks allowing interaction with your peers, poster presentation sessions, expert led case study presentations and incisive Q&A panel discussions during three separate tracks which will examine the topics below.

**Conference Agenda**

**Digital Pathology - Strategy and Technology**
- Introduction, benefits & future developments of Digital Pathology
- Implications on pathology practice
  - Uses in education and training
- Converting to/ integration of digital pathology
- Technology advances in digital pathology
- Digital Pathology project updates
- Standardisation in Digital Pathology
- Quality control and improvement
- Validation
- Insourcing
- Panel Discussion – Overcoming barriers in adoption of Digital pathology

**Pathology Informatics**
- Acquisition, processing, archiving & retrieval of WSI
- Cloud Computing
- Access through mobile devices
- Pathology PACS
- Automation
- Improving WSI workflow efficiency
- Telepathology
  - Virtual networks
  - Use in remote areas
- Telediagnosis
- Pathology IT

**Digital Image Analysis**
- Overcoming challenges in image analysis
  - Image standardization
  - Compression techniques
- Analysis software
- Automated image analysis
- Quantitative image analysis research
- Visualization methods for diagnosis and prognosis
- Annotation tools
- Pattern recognition
- Scoring
- Algorithm development / Image analysis algorithms

**Digital Pathology Applications and Research Case Studies**
- Research case studies utilizing digital pathology in
  - Clinical trials
  - Diagnosis
  - Diagnostics
  - Next generation sequencing
  - Biomarker analysis /research / quantification
  - Tissue-based research / imaging
  - Biobanking
  - Precision / personalised medicine
  - Image analysis

For more information please contact Steve Hambrook, Conference Director, Global Engage, steve@globalengage.co.uk +44 (0)1865 849841
Digital Pathology Congress USA – Confirmed Speakers

- Anil Parwani, Division Director, Pathology Informatics, Professor of Pathology and Biomedical Informatics, Shadyside Hospital, University of Pittsburgh Medical Centre, USA
- Yun-Fu Hu, Deputy Director, Division of Molecular Genetics and Pathology, Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA
- Andrew Evans, Associate Professor, Laboratory Medicine and Pathobiology, University Health Network (UHN), Toronto, Ontario, Canada
- Scott Binder, Pritzker Professor, Senior Vice Chair and Director of Pathology Clinical Services, UCLA
- Thomas Bauer, Director, ePathology; Medical Director, Cleveland Clinic
- Metin Gurcan, Associate Professor, Department of Biomedical Informatics, The Ohio State University, Columbus, OH, USA
- Robert Dunstan, Distinguished Investigator, Head, Translational Pathology Laboratory, Biogen Idec
- Jeroen van der Laak, Assistant Professor in Digital Pathology, Dept of Pathology, Radboud University Nijmegen Medical Centre, The Netherlands
- Christina Jamieson, Assistant Professor, Urology, Moores Cancer Center, UC, San Diego, USA
- Gerardo Fernandez, Associate Professor, Dept of Pathology & Dept of Genetics/Genomic Science, Icahn School of Medicine Mount Sinai Hospital
- Stephen S. Raab, Clinical Chief of Laboratory Medicine, Eastern Health, St. John’s, NL, Canada, Professor of Pathology, Memorial University of Newfoundland, St. John’s, NL, Canada, and Professor of Pathology, University of Washington, Seattle, WA, USA
- David Gutman, Assistant Professor, Biomedical Informatics, Emory University School of Medicine
- Clara Magyar, Director Image Analysis/Virtual Microscopy, Manager Translational Pathology Core Laboratory, UCLA
- Stephen Schmechel, Associate Professor, Department of Pathology, University of Washington School of Medicine, USA
- Keith Kaplan, Chief Medical Officer, Corista, Practicing Pathologist, Publisher, TissuePathology.com
- Kimberly Jewett, CEO & Founder, Kimberly Jewett Consulting, Inc.
- Yukako Yagi, Director of Pathology Imaging and Communication Technology Center, Massachusetts General Hospital, Assistant Professor of Pathology, Harvard Medical School, USA
- Toby Cornish, Assistant Professor of Pathology, Division of Gastrointestinal and Liver Pathology, Associate Director of the Pathology Informatics Division, Johns Hopkins School of Medicine, USA
- Matthew Theisen, Research Investigator, Molecular and Cellular Oncology, Takeda Oncology, Takeda Pharmaceuticals
- Chen Zhou, Clinical Associate Professor, Department of Pathology, British Columbia Cancer Agency, University of British Columbia, Vancouver, Canada
- Jaime Rodriguez-Canales, Assistant Professor, Director Immunohistochemistry and Digital Pathology Laboratory, Department of Translational Molecular Pathology, UT – MD Anderson Cancer Center
- Kurt A. Schalper, Associate Research Scientist, Departments of Pathology and Medical Oncology, Yale School of Medicine, Director Translational Immuno-oncology Laboratory (T.I.L.); Yale Cancer Center
- Anthony Magliocco, Chair of Anatomical Pathology, Anatomical Pathology Department, Moffitt Cancer Center
- William DeSalvo, Owner/Consultant, Collaborative Advantage Consulting
- Track Chair - Richard Levenson, Professor and Vice Chair for Strategic Technologies, Department of Pathology & Laboratory Medicine, UC Davis Medical Center
- Track Chair - Michael Valante, Group Innovation, Philips
- Track Chair – Scott Dieter, WindoPath Sales Representative, Psyche Systems Corporation
- Zoltan G. Laszik, Professor of Clinical Pathology, University of California, San Francisco
- Adam Smith, Application Scientist, Indica Labs
- David Byrd, VP, Business Development, XIFIN, Inc
- Mark Gustavson, Vice President, Diagnostics, MetaStat, Inc
- Stephen B. White, Vice President Global Sharing Solutions, Leica Biosystems

Digital Pathology Series

Digital Pathology Congress USA - June 22-23, 2015, San Diego, CA, USA
www.globalengage.co.uk/digitalpathology.html

Digital Pathology Congress Asia - September 21-22, 2015, Kuala Lumpur, Malaysia,
www.globalengage.co.uk/digital-pathology-asia.html

2nd Digital Pathology Congress Europe - December 3-4, 2015, London, UK
www.globalengage.co.uk/digital-pathology.html
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<th>Time</th>
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<tr>
<td>08.00-08.50</td>
<td>Registration &amp; Coffee - Town and Country Room</td>
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<tr>
<td>08.50-08.55</td>
<td>Global Engage Welcome Address – San Diego Room</td>
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<tr>
<td>08.55-09.00</td>
<td>Track Chair, Michael Vala, Group Innovation, Philips</td>
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| 09.00-09.40 | **Keynote Address:**  
The Emergence of Digital Pathology: Opportunities and Challenges  
Digital pathology has grown dramatically in the last 10 years and has created opportunities to not only support the triaging of difficult cases among specialists within an organization, but also enable remote pathology consultations with external organizations across the world. Many applications have emerged and as a result digital pathology is increasingly being used in both clinical and research areas. The focus of this talk will be on the number of exciting developments in this field in recent times and the challenges that lie ahead.  
Confirmed:  
Adam Smith, Application Scientist, Indica Labs  
Solution Provider Presentation  
Keynote Address:  
Alexandra, Application Scientist, Indica Labs  
Keynote Address:**  
FDA Regulation of Digital Pathology  
FDA has cleared or approved a number of digital pathology devices for different intended uses, such as digital read and image analysis of immunohistochemically stained tissue slides, classification and enumeration of peripheral blood cells, and initial screening of cervical cytology slides. FDA has been actively engaged in discussions with various stakeholders regarding whole slide imaging systems intended for primary diagnosis of H&E stained slides. To ensure that the images produced from H&E stained slides are safe and effective for use as an aid in primary diagnosis of cancer, FDA has maintained that WSI manufacturers should assess technical performance of the components in the imaging chain, and demonstrate analytical and clinical performance using a sufficient number of specimens and readers representative of the intended use populations. FDA has provided WSI manufacturers with outlines of various validation studies and performance measures.  
Confirmed:  
Yun-Fu Hu, Deputy Director, Division of Molecular Genetics and Pathology, Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA  
10.00-10.40 | Solution Provider Presentation  
Analysis of Immune Cell Populations in Tumours and Whole Tissue Sections Using HALO  
Tumour cells are able to escape host immunosurveillance using various molecular mechanisms. Therapies designed to overcome inhibitory mechanisms and boost the host anti-cancer immune cell response are available for a growing number of different cancer types. Increases in immune cell populations, particularly in the invasive tumour margin, have been associated with tumour regression in responding patients. Quantitative analysis data from HALO may be used to investigate new therapeutic targets or to identify patients most likely to respond to specific therapies.  
Confirmed:  
Adam Smith, Application Scientist, Indica Labs  
Sponsored by Indica Labs  
10.40-11.40 | Morning Refreshments – Town and Country Room                          |
|         | Morning Refreshments – Town and Country Room                          |
|         | Poster Presentation Sessions – Town and Country Room                   |
|         | Digital Pathology Strategy & Technology                                |
|         | Track Chair - Michael Valente, Group Innovation, Philips             |
|         | Pathology Informatics                                                 |
|         | Track Chair - Scott Dieter, WindoPath Sales Representative, Psyche Systems Corporation |
| 11.40-12.05 | **Niche Adoption of Digital Pathology at University Health Network:**  
The Journey from Frozen Sections to Primary Diagnosis  
University Health Network (UHN) is a multi-site academic healthcare institution in downtown Toronto. In addition to its downtown Toronto sites, the Laboratory Medicine Program at UHN provides diagnostic services to multiple partner hospitals outside of Toronto. While the vast majority of our diagnostic work is still done using glass slides and microscopes, UHN pathologists have been using telepathology to provide a variety of sub-specialty diagnostic services to various partner sites for over 10 years. Starting in 2004, a remote controlled static-dynamic robotic microscope was used to review frozen sections at one of our downtown Toronto sites. In 2006, we switched whole slide imaging (WSI) to review these frozen section frozen sections and have subsequently used WSI to review frozen sections from several partner sites outside of Toronto. As of 2012, we implemented WSI for primary diagnosis of selected cases originating at a partner site located 40 miles east of Toronto. This presentation will review the evolution of telepathology at UHN, focusing on the performance characteristics of each niche application and the lessons we have learned along the way.  
Confirmed:  
Andrew Evans, Staff Pathologist and Director of Telepathology, University Health Network, Toronto, Ontario, Canada  
CAD in Pathology: Closer Than You Think  
The introduction of digital pathology in primary diagnostics is still hampered by high costs. It is hypothesized that computer aided diagnosis (CAD) techniques will be the tipping point, leading to large scale introduction of digital scanning of histopathological slides. However, many pathologists are still skeptical about the possibilities of computers taking over part of their daily routine. In reality, the state-of-the-art of CAD in pathology is much further evolved than most pathologists may think. Modern pattern recognition techniques have accelerated research in this area enormously. Current algorithms are ready for evaluation in routine diagnostic situations and may significantly alleviate the work of the pathologist. This talk will show examples of algorithms and solutions for use of these techniques in daily practice.  
Confirmed:  
Jeroen van der Laak, Assistant Professor in Digital Pathology, Dept of Pathology, Radboud University Nijmegen Medical Centre, The Netherlands |
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<tr>
<td>12.05-12.30</td>
<td>Anatomic Pathology in Biopharma: Making the Change from Descriptive to Quantitative</td>
<td>For anatomic pathology to play an expanded role in modern diagnostic medicine and research, it needs to change from a descriptive to a primarily quantitative discipline. In biopharma, using whole slide images that serve as the basis for standardization of methods and quantifying morphologic alterations is commonplace. When methods are standardized, non-subjective quality control can be implemented. Consistent staining allows for the application of reproducible image analysis algorithms, resulting in a new, accurate way to look at structure. Standard in industry, these methods will inevitably be applied to diagnostic pathology. Herein, the transition of anatomic pathology from a descriptive to a quantitative discipline will be discussed, examples of image analysis using whole slide images will be presented and the value added will be demonstrated. Confirmed: Robert Dunstan, Distinguished Investigator, Head, Translational Pathology Laboratory, Biogen Idec</td>
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<td>12.30-13.00</td>
<td>Solution Provider Presentation Change in Expectation - Meeting New Demands</td>
<td>As the Wall Street Journal recently reported, &quot;pathologists are the most important doctors patients never meet&quot;. Papers published over the last few years underscore the inherent difficulty certain cases present and the amount of discordance that can occur in case interpretation. Thus, pathology is inherently collaborative: sharing cases with subspecialists is critical. Despite these realities, the industry still relies on century-old technology and decades old processes to share difficult cases. Confirming results can take weeks or longer if slides are misplaced, broken, or lost. Teleradiology changed market expectations overnight. Why should patients and the patient care team have to wait so long when digital pathology and other state of the art solutions are available to turns weeks to days, or even hours? Confirmed: Stephen B. White, Vice President Global Sharing Solutions, Leica Biosystems</td>
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<tr>
<td>13.00-14.00</td>
<td>Lunch – Town and Country Room Poster Presentation Sessions – Town and Country Room</td>
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<td>14.00-14.30</td>
<td>Solution Provider Presentation Validating Whole Slide Digital Imaging for Frozen Section Diagnoses</td>
<td>Whole slide digital images of frozen sections, comprising 541 randomly selected cases with 2158 slides across all subspecialties, were evaluated for image quality and diagnostic utility. Only one case was deemed non-diagnostic due to image quality problems on a touch prep specimen (0.18%), corresponding to one part out of 890 parts (0.1% total parts). Although 22 additional digital images of a total of 2167 frozen sections were also classified as non-diagnostic (1.0% of total slides), a diagnosis could still be rendered on all of these cases since images of level sections were of diagnostic quality. WSDI technology is applicable for frozen section diagnosis as digital images of 99.8% of cases out of a cohort of 547 unbiased randomly selected cases were interpreted as being diagnostic. Confirmed: Zoltan G. Laszik, Professor of Clinical Pathology, University of California, San Francisco</td>
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**Digital Pathology Image Analysis**

We are developing computerized image analysis systems to help pathologists in their evaluations of pathological images. Computerized analysis provides several advantages: speed, accuracy and consistency. Once a computerized system is developed, its performance can be assessed--on an independent set of cases--by comparing the output with expert readings, known as an open loop evaluation. Alternatively, readers can incorporate the computer output in their reading, potentially changing their decisions and therefore, closing the loop. In this discussion, we will present some of our projects at the Clinical Image Analysis Lab at The Ohio State University, USA (www.bmi.osu.edu/cialab); and provide an overview of techniques and methods, including the assessment of computerized image analysis systems. Confirmed: Metin Gurcan, Associate Professor, Department of Biomedical Informatics, The Ohio State University, Columbus, OH, USA

**Solution Provider Presentation**

For sponsorship opportunities please contact Steve Hambrook at steve@globalengage.co.uk

**Solution Provider Presentation**

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<th>Time</th>
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| 14.30-14.55 | **Role of Digital Pathology in a Changing World**<br>With increasing consolidation of pathology services and changes in reimbursement with fee-for-service models transitioning to outcomes-based models and other external market forces including consumer-driven healthcare, digital pathology is well-suited to meet the needs of both patients and providers. Increasingly larger integrated healthcare delivery networks require technologies to provide pathology services for patients across a greater distance with a high-degree of subspecialization. This program will focus on the value proposition for digital pathology for routine surgical pathology workflows with increasing demands placed on the system by payors and patients. Digital pathology has the ability to empower providers and patients and provide pathologists and laboratories an opportunity to re-establish their value in the healthcare system.  
Confirmed:  
Keith Kaplan, Chief Medical Officer, Corista, Practicing Pathologist, Publisher, TissuePathology.com |
| 14.55-15.20 | **The Role of Digital Pathology and the Impact on Patients With Cancer**<br>Digital pathology is an integrated solution to empowering patients and their families. The struggles patients face during their journey with cancer allow us to recognize the impact of this integrated solution that can benefit both patients and healthcare providers. The focus will be on the role of digital pathology and need/impact for second opinion consults from a patient’s perspective and review the role pathologists, histotechnologists and laboratories play during a patient’s journey through a patient point of view.  
Confirmed:  
Kimberly Jewett, CEO & Founder, Kimberly Jewett Consulting, Inc. |
| 15.20-15.50 | **Panel Discussion – Overcoming Barriers in Adoption of Digital Pathology**  
Confirmed:  
Chair - Keith Kaplan, Chief Medical Officer, Corista, Practicing Pathologist, Publisher, TissuePathology.com  
Anil Parwani, Division Director, Pathology Informatics, Professor of Pathology and Biomedical Informatics, Shadyside Hospital, University of Pittsburgh Medical Centre, USA  
Jaime Rodriguez-Canales, Assistant Professor, Director Immunohistochemistry and Digital Pathology Laboratory, Department of Translational Molecular Pathology, UT – MD Anderson Cancer Center  
Scott Binder, Pritzker Professor, Senior Vice Chair and Director of Pathology Clinical Services, UCLA  
Yukako Yagi, Director of Pathology Imaging and Communication Technology Center, Massachusetts General Hospital, Assistant Professor of Pathology, Harvard Medical School, USA |
| 15.50-16.40 | **Afternoon Refreshments – Town and Country Room**  
**Poster Presentation Sessions – Town and Country Room** |
| 16.40-17.10 | **Solution Provider Presentation**  
**Consolidated Reporting for Pathologists' Led Multidisciplinary Collaboration**  
Data show that when physicians across multiple disciplines (pathology, radiology, and oncology) collaborate, diagnoses are changed as much as 40% of the time. Pathologists are at the forefront in providing consolidated diagnostic reports integrating pathology and radiologist findings for increased accuracy. XIFIN’s collaborative medicine portal enables communication across physician specialties in a secure cloud environment.  
Confirmed:  
David Byrd, VP, Business Development, XIFIN Inc  
Sponsored by Xifin |
| 16.40-17.10 | **Solution Provider Presentation**  
For sponsorship opportunities please contact Steve Hambrook at steve@globalengage.co.uk |
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<th>Summary</th>
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<tr>
<td>17.10-17.35</td>
<td>Challenges and Caveats in the Application of Digital Pathology Systems for Biomarker Analysis in Tissue Specimens</td>
<td>Jaime Rodriguez-Canales, Assistant Professor, Director Immunohistochemistry and Digital Pathology Laboratory, Department of Translational Molecular Pathology, UT – MD Anderson Cancer Center</td>
<td>An important aim in translational pathology is the discovery of novel biomarkers in tissue samples. A traditional method for biomarker analysis is based on the immunohistochemistry (IHC) staining of human tissue sections evaluated with light microscopy by a pathologist, providing a semiquantitative scoring. However, this method is subjective and effort consuming. The current development of digital pathology systems, including faster scanners and powerful image analysis software, provide an important tool for biomarker evaluation. However, the application of image analysis requires a higher quality and consistency of IHC. Furthermore, digital pathology demands a new role for the pathologist who has to provide a rigorous quality control and selection of markers and type of image analysis techniques in order to provide reliable and useful data. Confirmed: Jaime Rodriguez-Canales, Assistant Professor, Director Immunohistochemistry and Digital Pathology Laboratory, Department of Translational Molecular Pathology, UT – MD Anderson Cancer Center</td>
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<tr>
<td>17.35-18.00</td>
<td>Challenges and Opportunities for Quantitative Digital Image Analysis for use in the CLIA Pathology Laboratory</td>
<td>Anthony Magliocco, Chair of Anatomical Pathology, Anatomical Pathology Department, Moffitt Cancer Center</td>
<td>Digital pathology has made remarkable advances as a tool to improve assessment of clinical specimens and to accurately measure expression of protein biomarkers in-situ in standard tissue preparations. However there are numerous barriers to the routine incorporation of these methods in to standard CLIA laboratories. I will review current usage, challenges and future opportunities. Confirmed: Anthony Magliocco, Chair of Anatomical Pathology, Anatomical Pathology Department, Moffitt Cancer Center</td>
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<td>18.00-18.25</td>
<td>Digital Pathology as a Transformational Quality Assurance Tool</td>
<td>Stephen S. Raab, Clinical Chief of Laboratory Medicine, Eastern Health, St. John’s, NL, Canada, Professor of Pathology, Memorial University of Newfoundland, St. John’s, NL, Canada, and Professor of Pathology, University of Washington, Seattle, WA, USA</td>
<td>Digital pathology potentially is a disruptive tool when used as a quality assurance and improvement method. Digital pathology implementation may lead to marked changes in anatomic laboratory work-flow, pathologist activities, and teamwork, which improve patient safety, efficiency, effectiveness of care, and timeliness of diagnosis. Confirmed: Stephen S. Raab, Clinical Chief of Laboratory Medicine, Eastern Health, St. John’s, NL, Canada, Professor of Pathology, Memorial University of Newfoundland, St. John’s, NL, Canada, and Professor of Pathology, University of Washington, Seattle, WA, USA</td>
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<td>18.30-19.30</td>
<td>Chairman’s Closing Remarks and End of Day 1</td>
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<td>08.20-09.00</td>
<td>Morning Coffee – Town and Country Room</td>
<td>San Diego Room - Track Chair - Richard Levenson, Professor and Vice Chair for Strategic Technologies, Department of Pathology &amp; Laboratory Medicine, UC Davis Medical Center</td>
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<tr>
<td>09.00-09.35</td>
<td>Keynote Address: Telepathology in China— A 5 Year Perspective—Over 2000 Cases Now in Los Angeles, CA</td>
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<td>09.35-10.00</td>
<td>Approaches to and Perspectives on Digital Insourcing of Pathology Consultation and Second Opinion</td>
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<td>10.00-10.30</td>
<td>Development of High-Throughput Image Analysis Algorithms for Automated Identification and Quantification of Complex Multicellular Structures</td>
<td>San Diego Room - Track Chair - Richard Levenson, Professor and Vice Chair for Strategic Technologies, Department of Pathology &amp; Laboratory Medicine, UC Davis Medical Center</td>
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<tr>
<td>10.30-11.30</td>
<td>Implementing Whole Slide Imaging for the Remote Interpretation of Frozen Sections and for International Consultations in Surgical Pathology</td>
<td>San Diego Room - Track Chair - Richard Levenson, Professor and Vice Chair for Strategic Technologies, Department of Pathology &amp; Laboratory Medicine, UC Davis Medical Center</td>
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<td>11.30-11.55</td>
<td>A Nationwide Telepathology Consultation Network in China: Implementation and Result Analysis</td>
<td>San Diego Room - Track Chair - Richard Levenson, Professor and Vice Chair for Strategic Technologies, Department of Pathology &amp; Laboratory Medicine, UC Davis Medical Center</td>
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<tr>
<td>11.55-12.20</td>
<td>Integration of Whole Slide Imaging and Image Analysis in a Core Research Facility</td>
<td>San Diego Room - Track Chair - Richard Levenson, Professor and Vice Chair for Strategic Technologies, Department of Pathology &amp; Laboratory Medicine, UC Davis Medical Center</td>
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### Understanding the Tumor Immune Microenvironment in Solid Tumors Using Multispectral Immunofluorescence and Quantitative Analysis

Understanding the tumor immune microenvironment could support the optimal use of novel anti-cancer immunostimulatory therapies. In situ detection of immune inhibitory molecules and immune cells in the tumor allows signal measurement with preservation of key contextual (morphological) information. Strategies for objective and quantitative assessment of actionable immune targets and immune cell subpopulations in formalin-fixed tumor specimens by multispectral fluorescence and automated analysis will be presented.

**Confirmed:** Kurt A. Schalper, Associate Research Scientist, Departments of Pathology and Medical Oncology, Yale School of Medicine, Director Translational Immunomuno-oncology Laboratory (T.I.L.), Yale Cancer Center

### Preclinical Assay Development to Support IHC-Based Biomarkers for Oncology

Quantitative Digital Pathology enables the quantitative analysis of biomarker expression and localization in tissue samples. Digital Pathology combines numerous technologies including IHC autostainers, digital slide scanners, and image analysis software. These IHC-based biomarker assays drive lead optimization efforts in preclinical studies, and help gain a better understanding of target inhibition in human samples. This presentation will highlight the image analysis workflow and assay development activities for the preclinical assay, and the transition from a preclinical assay to a clinical biomarker assay.

- Highlight image analysis in the context of a pharmacodynamic (PD) assay workflow.
- PD Case Study highlighting routine and custom image analysis development for tumor and skin samples.
- IHC biomarker screen in select tumors for Translational Medicine clinical assay validation.

**Confirmed:** Matthew Theisen, Research Investigator, Molecular and Cellular Oncology, Takeda Oncology, Takeda Pharmaceuticals

### Tumor Infiltrating B-cells are Increased in Prostate Cancer Tissue

We investigated the density of infiltrating B cells within human PCA for which we developed a new reproducible and quantitative computational method. Tumor infiltrating lymphocytes (TILs), particularly CD8+ T cells, have been shown to have strong positive prognostic relevance in multiple other solid tumors. However, the role of B-cell immunity in prostate cancer is not well understood, and represents an opportunity for study and potential therapy. Our study showed that higher B-cell infiltration was present within the intra-tumoral PCA regions compared to the extra-tumoral benign prostate tissue regions in prostatectomy sections. This method is being used for digital computer assisted analysis of immunohistochemical staining of additional B-cell promoting mechanism of recurrence biomarkers in PCA specimens and could be used for any solid tumor.

**Confirmed:** Christina Jamieson, Assistant Professor, Urology, Moores Cancer Center, UC, San Diego, USA

### Slide-Free Pathology via MUSE: UV Surface Excitation Microscopy for Imaging Unsectioned Tissue

MUSE (microscopy with UV surface excitation) generates diagnostic-quality histological images, with enhanced content, from fresh or fixed, but unsectioned tissue, rapidly, simply and inexpensively. UV excitation, that penetrates only to a depth of a few microns, removes the need for histology and sectioning. MUSE can image fresh or fixed tissues after brief (seconds) staining with fluorescent tissue dyes such as eosin and DAPI. A conventional color camera captures the resulting high-resolution fluorescence images convertible in real time to resemble H&E. This sample-sparing method ensures availability of tissue for downstream analyses. With a scanning stage “whole-slide-equivalent” images can be created. MUSE should be useful in hospitals and clinics, physician offices, low-resource settings, as well as in the general research community.

**Confirmed:** Richard Levenson, Professor and Vice Chair for Strategic Technologies, Department of Pathology & Laboratory Medicine, UC Davis Medical Center

### Creating Collaborative Quality Improvement Using Digital Pathology

The workshop will address the issues and barriers that can destroy the implementation of the digital pathology solution; utilizing the positive aspects of digital pathology technology; working to slow or stop the vital change solution required to move Anatomic Pathology from THE WAY IT IS to THE WAY IT NEEDS TO BE. We must address the fundamental changes needed to the Histotechnology process that will support a stable structure, where each step and task are dependent on each other and share the burden of quality control and assurance. There will be discussion of the importance of standardization and quality process improvement in Histotechnology and its significance to the success of implementing a digital pathology solution; utilizing the positive aspects of digital pathology technology; developing the Histotechnology improvement process, on a day to day basis, to improve overall efficiency and quality documentation and how collaborative quality will combine digital pathology technology and process improvement techniques to aid in the development of a continuous quality assurance program for routine, special and IHC stains.

**Steps in Creating Collaborative Quality:**
- Reduction of Variables; Data, Metrics and Measurement; Process Analysis; Process Structure; Interoperability
- Gain understanding of the importance of standardization and process improvement in the pre-analytical steps
- Learn to apply appropriate quality and process improvement techniques
- Understand the value of quality improvement to the implementation process

**Confirmed:** William DeSalvo, Owner/Consultant, Collaborative Advantage Consulting