## FRIDAY 5 MAY 2017

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Title</th>
<th>Chair/Presenter</th>
<th>Institution/Location</th>
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<tr>
<td>8:00</td>
<td></td>
<td>Registration and breakfast</td>
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<td>9:00</td>
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<td><strong>Workshop opening</strong></td>
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<td>9:10</td>
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<td><strong>Opening lecture: A pathologist, a radiologist and a hepatologist walked into a bar</strong></td>
<td>Brent Neuschwander-Tetri, MD</td>
<td>Saint Louis University Health Sciences Center, St. Louis, MO, USA</td>
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<td>9:40</td>
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<td><strong>Innovation in histological assessment of NASH</strong></td>
<td>Pierre Bedossa, MD, PhD</td>
<td>University of Paris-Diderot, Paris, France</td>
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<td>10:00</td>
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<td><strong>Panel discussion: Many perspectives, one goal</strong></td>
<td>Veronica Miller, PhD - Forum for Collaborative HIV Research; Arun Sanyal, MD, MBBS - Virginia Commonwealth University</td>
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<td><strong>Moderators:</strong></td>
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<td>Veronica Miller, PhD - Forum for Collaborative HIV Research</td>
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<td>Arun Sanyal, MD, MBBS - Virginia Commonwealth University</td>
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<td><strong>Panel members:</strong></td>
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<td>Brent Neuschwander-Tetri, MD - Saint Louis University Health Sciences Center</td>
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<td>Pierre Bedossa, MD, PhD - University of Paris-Diderot</td>
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<td>David Kleiner, MD, PhD - Center for Cancer Research, National Cancer Institute</td>
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<td>Sophie Megnien, MD - Genfit SA</td>
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<td>11:00</td>
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<td><strong>Coffee break</strong></td>
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<th>Session 2 Chairs</th>
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<tr>
<td>11:30</td>
<td><strong>View from the Top - Potential impact of 21st century cures act</strong></td>
<td>Peter Stein, MD</td>
<td>FDA Center for Drug Evaluation and Research, Silver Spring, MD, USA</td>
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<td>12:00</td>
<td><strong>EU perspective</strong></td>
<td>Elmer Schabel, MD</td>
<td>European Medicines Agency, London, UK &amp; BfArM, Bonn, Germany</td>
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<td>12:15</td>
<td><strong>Discussion</strong></td>
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<td>12:30</td>
<td><strong>Collaboration in action - Biomarkers Endpoints &amp; other Tools Resource</strong></td>
<td>Chris Leptak, MD, PhD</td>
<td>FDA Center for Drug Evaluation and Research, Silver Spring, MD, USA</td>
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<td>12:40</td>
<td><strong>Collaboration in action - Foundation for the National Institutes of Health</strong></td>
<td>Roberto Calle, MD, FACE, FACP</td>
<td>Foundation for the National Institutes of Health, Bethesda, MD, USA</td>
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<td>12:50</td>
<td><strong>Collaboration in action - Innovative Medicines Initiative</strong></td>
<td>Quentin Anstee, BSc, MB BS, PhD, MRCPIUKI, FRCP</td>
<td>Newcastle University, Newcastle, United Kingdom</td>
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13:00  **Panel discussion: Building synergy across the Atlantic**
Moderators:
Chris Leptak, MD, PhD - FDA Center for Drug Evaluation and Research
Veronica Miller, PhD - Forum for Collaborative HIV Research
Panel members:
Peter Stein, MD - FDA Center for Drug Evaluation and Research
Roberto Calle, MD, FACE, FACP - Foundation for the National Institutes of Health
Quentin Anstee, BSc, MB BS, PhD, MRCP(UK), FRCP - Newcastle University

13:30  Group picture

13:40  Lunch break

14:15  **Poster viewing**

**Session 3**  **Circulating biomarkers**
Chairs: Sudha Shankar & Brent Neuschwander-Tetri

15:00  **Lipidomics and proteomics**
Puneet Puri, MD
Virginia Commonwealth University, Richmond, VA, USA

15:20  **Role of genetic assessments**
Quentin Anstee, BSc, MB BS, PhD, MRCP(UK), FRCP
Newcastle University, Newcastle, United Kingdom

15:40  **Circulating nucleic acids and combination panels**
Sven Francque, MD, PhD
Antwerp University Hospital, Antwerp, Belgium

16:00  Discussion

16:30  Coffee break

**Session 4**  **Imaging biomarkers**
Chairs: Quentin Anstee & Lara Dimick-Santos

17:00  **MRI; what can it deliver**
Claude Sirlin, MD
UC San Diego, San Diego, CA, USA

17:20  **Transient elastography & other techniques**
Raj Vuppalanchi, MBBS
Indiana University School of Medicine, Indianapolis, IN, USA

17:40  Abstract-driven presentations

**Hepatic proton density fat fraction correlates with histologic measures of steatosis and is responsive to change in those measures in a multi-center nonalcoholic steatohepatitis clinical trial**
Michael Middleton, USA
A meta-analysis on repeatability of magnetic resonance elastography of liver
Suraj Serai, USA #02

18:00 Panel discussion
Moderators:
Quentin Anstee, BSc, MB BS, PhD, MRCP(UK), FRCP - Newcastle University
Lara Dimick-Santos, MD - FDA Center for Drug Evaluation and Research
Panel members:
Claude Sirlin, MD - UC San Diego
Raj Vuppalanchi, MBBS - Indiana University School of Medicine
Daniel Krainak, PhD - FDA Center for Devices and Radiological Health

18:30 Welcome reception

19:00 Workshop dinner

SATURDAY 6 MAY 2017

7:15 Registration desk open and walk-in breakfast

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<th>Session 5</th>
<th>Quantative assessment of hepatic health</th>
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<td>Chairs</td>
<td>Roberto Calle &amp; Puneet Puri</td>
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8:00 Breath tests
Shadab Siddiqui, MD
Virginia Commonwealth University, Richmond, VA, USA

8:15 Principles of kinetic measures
Greg Everson, MD, FACP
University of Colorado Denver, Denver, CO, USA

8:30 Abstract-driven presentations

A real-world, observational cohort of patients with nonalcoholic fatty liver disease: The TARGET-NASH study
Miriam Vos, USA #03

Novel multiparametric magnetic resonance elastography (MRE) protocol accurately predicts NAS score for NASH diagnosis
Alina Allen, USA #04

The comparisons of non-invasive markers for assessing fibrosis in Asian patients with nonalcoholic fatty liver disease
Jun Yong Park, South Korea #05

Serum GP73 as a surrogate biomarker of significant liver fibrosis and cirrhosis in NAFLD
Fengmin Lu, China #06

Plasma collagen type III (Pro-C3) levels associate with severity of histological features of non-alcoholic steatohepatitis and fibrosis within the screening population from the CENTAUR study
Pamela Vig, USA #07
9:20  **Panel discussion: Learning from functional, imaging and circulating biomarkers - Challenges of qualification in absence of highly effective therapy**  
Moderators:  
Roberto Calle, MD, FACE, FACP - Foundation for the National Institutes of Health  
Puneet Puri, MD - Virginia Commonwealth University  
Panel members:  
Shadab Siddiqui, MD - Virginia Commonwealth University  
Greg Everson, MD, FACP - University of Colorado Denver  
Eric Lefebvre, MD - Allergan  
Chris Leptak, MD, PhD - FDA Center for Drug Evaluation and Research  
Irene Tebbs, PhD - FDA Center for Devices and Radiological Health

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<th>Time</th>
<th>Session 6 Chairs</th>
<th>Challenges &amp; opportunities in integrating ‘OMICS</th>
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<td>10:00</td>
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| 10:30 | Pierre Bedossa & Shadab Siddiqui | Big data vs. the individual liver - regulatory perspective  
Robert Schuck, PharmD, PhD  
FDA Center for Drug Evaluation & Research, Silver Spring, MD, USA  
Big data vs. the individual liver - developer’s perspective  
José María Mato de la Paz, PhD  
OWL Metabolomics, Derio, Spain |  
| 11:00 |                  | Future scenarios of algorithm building  
Tom Travison, PhD  
Harvard Medical School & Hebrew SeniorLife Institute for Aging Research, Boston, MA, USA |  
| 11:15 |                  | Abstract-driven presentations  
Next-Generation Sequencing (NGS) of two independent cohorts identifies eleven circulating miRNAs for diagnosis of NASH and fibrosis  
Sven Francque, Belgium  
A new non-invasive diagnostic score to monitor change in disease activity and predict fibrosis evolution in patients with NASH  
Stephen Harrison, USA  
A precision medicine approach to comprehensive NAFLD diagnosis via metabolomics-based liquid biopsy  
Pablo Ortiz, Spain |  
| 11:45 |                  | Discussion |  
| 12:15 |                  | Lunch break & poster viewing |
### Session 7

**Chairs**
Veronica Miller & Arun Sanyal

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<tr>
<td>13:15</td>
<td><strong>Integrated assessment of diabetes, cardiovascular and liver risks and its</strong></td>
<td>Arun Sanyal, MD, MBBS</td>
<td>Virginia Commonwealth University, Richmond, VA, USA</td>
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<td>potential application in the clinical management of NAFLD</td>
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<td>13:55</td>
<td><strong>Navigating NASH biomarkers: From discovery to clinical practice</strong></td>
<td>John Sninsky, PhD</td>
<td>CareDx, Brisbane, CA, USA</td>
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| 14:15 | **Round table discussion: The way forward**                                | Moderators:
Veronica Miller, PhD - Forum for Collaborative HIV Research
Arun Sanyal, MD, MBBS - Virginia Commonwealth University
Panel members:
Raffi Werner, MD - Exalenz Bioscience
Claude Cohen-Bacrie, PhD - SuperSonic Imagine
Elizabeth Fagan - Perspectum Diagnostics
Céline Fournier, PhD - Echosens
Rémi Hanf, PhD - Genfit
Pablo Ortiz, MD, PhD - OWL Metabolomics
Steve Williams, MD, PhD - Somalogic
John Sninsky, PhD - CareDx |
| 15:00 | **Workshop closure**                                                        |                                                                              |                                                    |