

**THE FORUM**  
For Collaborative Research<sup>SM</sup>

# Liver Forum 15

**September 6, 2023**

*Institut Pasteur*

Veronica Miller, PhD  
Director

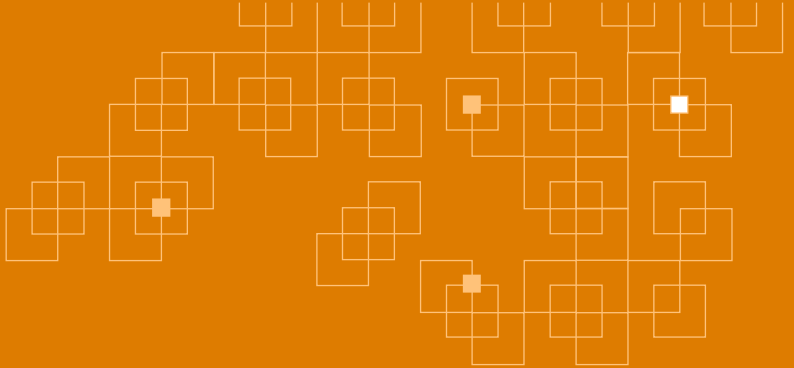
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# Session I: Welcome & Introductory Remarks

*Veronica Miller, Forum for Collaborative Research*

*Arun Sanyal, Virginia Commonwealth University*

*Judith Ertle, Boehringer Ingelheim*

# Overview of the Liver Forum

- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for NAFLD/NASH
- **How:** provide a neutral, independent, safe space for discussion and deliberation across stakeholder groups
  - Focus on developing consensus, increasing synergy and collaboration, and reducing duplication and uncertainty
  - Ongoing working group activity throughout the year anchored by larger project events
  - Active & engaged participation



# Forum Operating Principles

- Independent and neutral venue
  - Ongoing multi-stakeholder dialogue
  - Each stakeholder group has an equal voice
- Facilitate best science-based decisions, in real time
  - Break down inefficiencies and redundancy
  - Increase clarity, collaboration and innovation
  - Benefit to whole field, especially patients

# Forum = Safe Space

- Closed meeting
  - No marketing
  - No press
- Bring your expertise
  - Leave your “hat” at the door

# Rules of the Room and Zoom

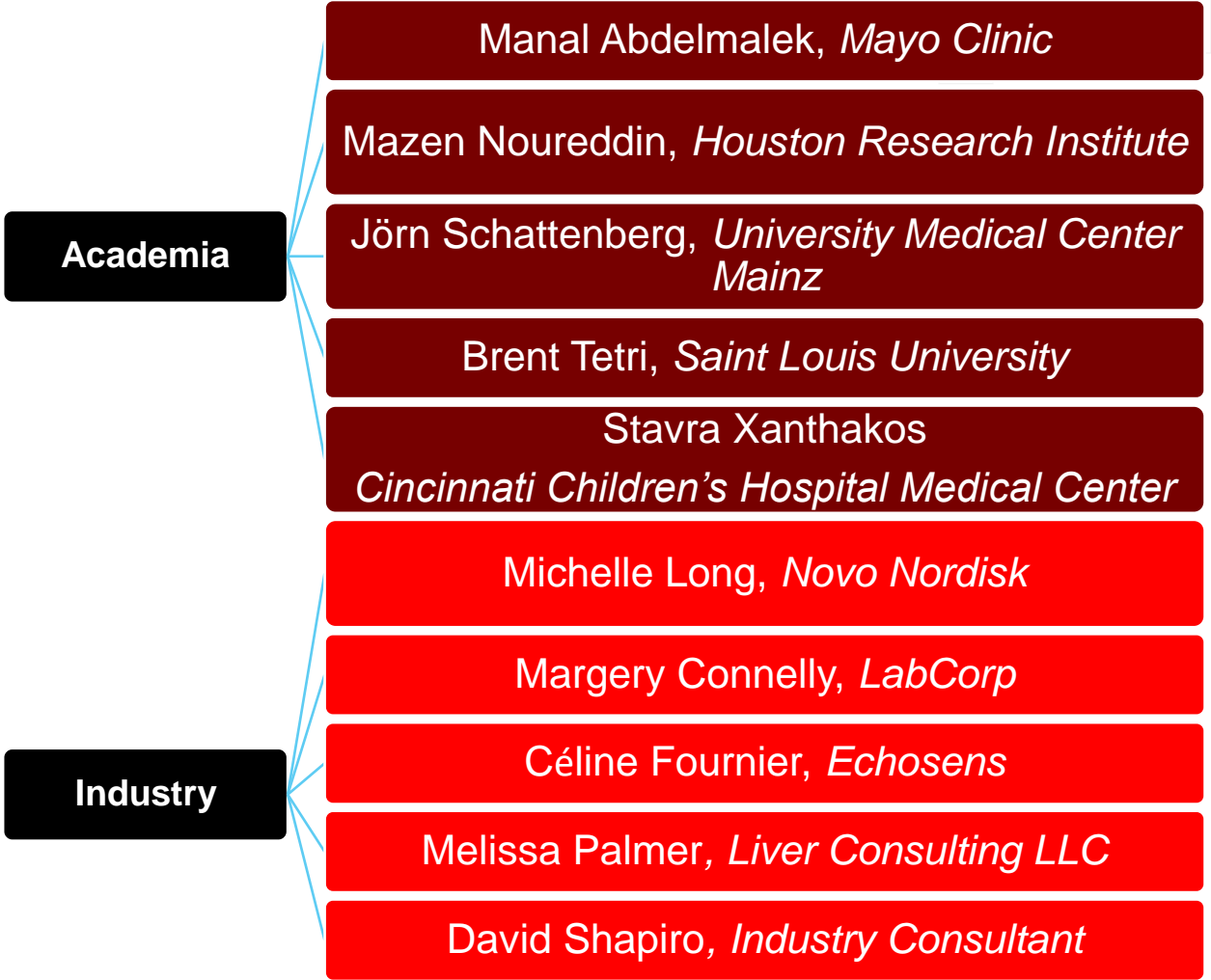
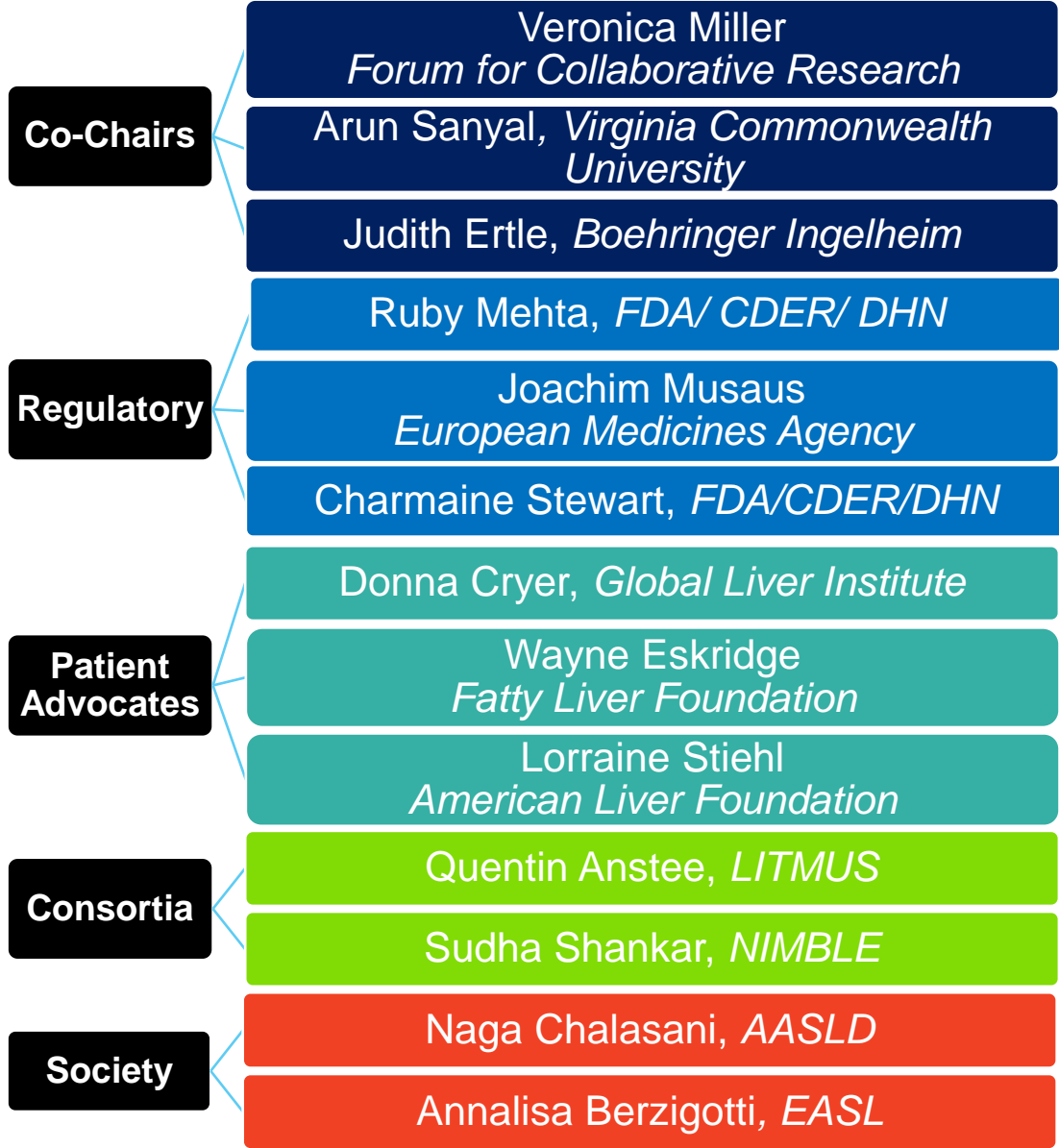
**What's said in the room, stays in the room**

**What's said in the room, is not for attribution**

**Let the science speak**

**Active participation**

# Steering Committee





# Liver Forum Sponsors



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# Forum Team

- Veronica Miller – Director
- Brenda Rodriguez – Deputy Director
- Azza Karrar – Senior Research Associate
- Logan Donaldson – Research Associate
- Sehyr Khan – Research Associate
- Mitchell Leus – Research Associate
- Shilpa Mitra – Research Associate
- Nicholas Murdock – Research Associate
- Alicia Jellinek – Program Financial Analyst
- Christopher Berry – Events Manager
- Donnice Butler – Senior Administrative Assistant
- Robin Schaefer – Postdoctoral Scholar
- Chris Hoffman – IT and Operational Director
- Margot Yann – Lead Data Scientist
- Zachary Rooney – Research Associate
- Sammy Berman – Research Data Analyst
- Jeffrey S. Murray – Program Advisor
- John Sninsky – Program Advisor
- Alessi Ayvaz – Student Researcher
- Danielle Howard Stewart – Graduate Student Researcher
- Andriana Marijic Buljubasic – Graduate Student Researcher



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# Review of Liver Forum 15 Goals and Objectives

*Veronica Miller, Forum for Collaborative Research*

# Goals for Today

- Develop clarity on MASLD/MASH nomenclature -- drug development
  - Regulatory, industry, patient perspectives
  - In collaboration with AASLD and EASL
- Support transition to non-invasive approach to MASH
- Stimulate new thinking re diagnostics
- Update on working group activities
  - Life/soul of LF!
- LBNL: Walk away with new insights, colleagues and collaborations!



# Session II: Steatotic Liver Diseases: Review of New Nomenclature from Multi-Stakeholders Perspectives

## **Moderators:**

***Veronica Miller, Forum for Collaborative Research***

***Jörn Schattenberg, University Medical Center Mainz***

# Journal Pre-proof

A multi-society Delphi consensus statement on new fatty liver disease nomenclature

Mary E. Rinella, Jeffrey V. Lazarus, Vlad Ratziu, Sven M. Francque, Arun J. Sanyal, Fasiha Kanwal, Diana Romero, Manal F. Abdelmalek, Quentin M. Anstee, Juan Pablo Arab, Marco Arrese, Ramon Bataller, Ulrich Beuers, Jerome Boursier, Elisabetta Bugianesi, Christopher D. Byrne, Graciela E. Castro Narro, Abhijit Chowdhury, Helena Cortez-Pinto, Donna Cryer, Kenneth Cusi, Mohamed El-Kassas, Samuel Klein, Wayne Eskridge, Jiangao Fan, Samer Gawrieh, Cynthia D. Guy, Stephen A. Harrison, Seung Up Kim, Bart Koot, Marko Korenjak, Kris Kowdley, Florence Lacaille, Rohit Loomba, Robert Mitchell-Thain, Timothy R. Morgan, Elisabeth Powell, Michael Roden, Manuel Romero-Gómez, Marcelo Silva, Shivaram Prasad Singh, Silvia C. Sookoian, C. Wendy Spearman, Dina Tiniakos, Luca Valenti, Miriam B. Vos, Vincent Wai-Sun Wong, Stavra Xanthakos, Yusuf Yilmaz, Zobair Younossi, Ansley Hobbs, Marcela Villota-Rivas, Philip N. Newsome, senior, on behalf of the NAFLD Nomenclature consensus group



| Recipient First Name | Recipient Last Name   | Country              |
|----------------------|-----------------------|----------------------|
| Manal                | Abdelmalek            | United States        |
| Leon                 | Adams                 | Australia            |
| Veeral               | Ajmera                | United States        |
| Mamun                | Al Mahtab             | Bangladesh           |
| William              | Alazawi               | United Kingdom       |
| Maryam               | Alkhatry              | United Arab Emirates |
| Naim                 | Alkhouri              | United States        |
| Alina                | Allen                 | United States        |
| Michael              | Allison               | United Kingdom       |
| Khalid               | Alswat                | Saudi Arabia         |
| Michele              | Alves-Bezerra         | United States        |
| Quentin              | Anstee                | United Kingdom       |
| Juan Pablo           | Arab                  | Canada               |
| Matthew J.           | Armstrong             | United Kingdom       |
| Marco                | Arrese                | Chile                |
| Diego                | Arufe                 | Argentina            |
| Pablo                | Aschner               | Colombia             |
| Amon                 | Asgharpour            | United States        |
| Gyorgy               | Baffy                 | United States        |
| Maya                 | Balakrishnan          | United States        |
| Meena                | Bansal                | United States        |
| Pierre               | Bedossa               | United States        |
| Cynthia              | Behling               | United States        |
| Renata               | Belfort               | United States        |
| Carlos               | Benítez               | Chile                |
| Thomas               | Berg                  | Germany              |
| Annalisa             | Berzigotti            | Germany              |
| Michael              | Betel                 | United States        |
| Ulrich               | Beuers                | Netherlands          |
| Cristiana            | Bianco                | Italy                |
| Jerome               | Boursier              | France               |
| Clifford             | Brass                 | United States        |
| Carol L.             | Brosgart              | United States        |
| Elizabeth Matthews   | Brunt                 | United States        |
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| Maria                | Buti                  | Spain                |
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| Steve                | Caldwell              | United States        |
| Rotonya              | Carr                  | United States        |
| Teresa               | Casanovas             | Spain                |
| Marlene              | Castellanos-Fernández | Cuba                 |

| Laurent     | Castera               | France        |
|-------------|-----------------------|---------------|
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| Cyrielle    | Caussy                | France        |
| Eira        | Cerda                 | México        |
| Naga        | Chalasanani           | United States |
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| Phunchai    | Charatcharoenwitthaya | Thailand      |
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| Amanda      | Cheung                | United States |
| Daniela     | Chiodi                | Argentina     |
| Ray         | Chung                 | United States |
| David       | Cohen                 | United States |
| Kathleen    | Corey                 | United States |
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| Donna       | Cryer                 | United States |
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| Anuradha    | Dassanayake           | Sri Lanka     |
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| Robert      | De Knegt              | Netherlands   |
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| Mohammed    | El-Kassas             | Egypt         |
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| Maria Lucia | Ferraz                | Brazil        |
| Yasser      | Fouad                 | Egypt         |
| Sven        | Francque              | Belgium       |
| Dave        | Frank                 | United States |
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| Michael     | Fuchs                 | United States |
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| Nicolas   | Goossens      | Switzerland    |
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| Cynthia   | Guy           | United States  |
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| Stephen   | Harrison      | United States  |
| Zachary   | Henry         | United States  |
| Bela      | Hunyady       | Hungary        |
| Alan      | Hutchison     | United States  |
| Scott     | Isaacs        | United States  |
| Jidong    | Jia           | China          |
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| Fasiha    | Kanwal        | United States  |
| Cynthia   | Kemp          | United States  |
| Denise    | Kile          | United States  |
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| Seung Up  | Kim           | South Korea    |
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| David     | Kleiner       | United States  |
| Rohit     | Kohli         | United States  |
| Bart      | Koot          | Netherlands    |
| Yannoula  | Koulla        | Cyprus         |
| Marcelo   | Kugelmas      | United States  |
| Joel      | Lavine        | United States  |
| Jeffrey   | Lazarus       | Spain          |
| Mariana   | Lazo          | United States  |
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| Juanita              | Perez Escobar             | Mexico          |
| Gianluca             | Perseghin                 | Italy           |
| Mario                | Pessoa                    | Brazil          |
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| Manuel           | Romero Gomez         | Spain          |
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| Ian              | Rowe                 | United Kingdom |
| Riina            | Salupere             | Estonia        |
| Arun             | Sanyal               | United States  |
| Shiv Kumar       | Sarin                | India          |
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| Jeff             | Schwimmer            | United States  |
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| Lawrence         | Serfaty              | France         |
| David            | Shapiro              | United States  |
| Marcelo          | Silva                | Buenos Aires   |
| Ashwani K.       | Singal               | United States  |
| Shivaramn Prasad | Singh                | India          |
| Lubomir          | Skladany             | Slovakia       |
| Silvia           | Sookoian             | Argentina      |
| Norbert          | Stefan               | Germany        |
| Jonathan         | Stine                | United States  |
| Shikha           | Sundaram             | United States  |
| C. Wendy         | Spearman             | South Africa   |
| Gianluca         | Svegliati-Baroni     | Italy          |
| Gyonzgi          | Szabo                | United States  |
| Frank            | Tacke                | Germany        |
| Tawesak          | Tanwandee            | Thailand       |
| Giovanni         | Targher              | Italy          |
| Brent            | Tetri                | United States  |
| Maja             | Thiele               | Denmark        |
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| Baron            | Tisthammer           | United States  |
| Aldo             | Torre Delgadillo     | Mexico         |
| Diane            | Tovar                | United States  |
| Michael          | Trauner              | Austria        |
| Emmanuel         | Tsochatzis           | United Kingdom |
| Luca             | Valenti              | Italy          |
| Laurens          | Van Kleef            | Netherlands    |
| Saskia           | Van Mil              | Netherlands    |
| Lisa             | VanWagner            | United States  |
| Adriana          | Varon Puerta         | Colombia       |
| Jose Antonio     | Velarde Ruiz Velasco | Mexico         |
| Mette            | Vesterhus            | Norway         |
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| Anthony          | Villiotti            | United States  |

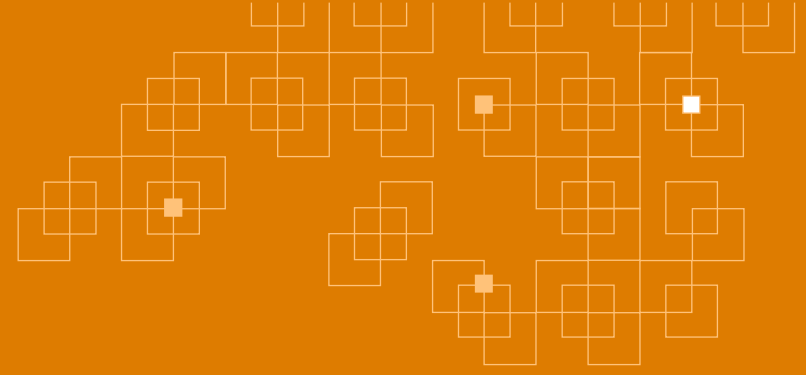
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|----------|-------------|----------------|
| Miriam   | Vos         | United States  |
| Kymberly | Watt        | United States  |
| Julia    | Wattacheril | United States  |
| Fonda    | Wilkins     | United States  |
| José     | Willemse    | Netherlands    |
| Vincent  | Wong        | China          |
| Stavra   | Xanthakos   | United States  |
| Yusuf    | Yilmaz      | Turkey         |
| Lorna    | Younger     | United States  |
| Zobair   | Younossi    | United States  |
| Amany    | Zekry       | United Kingdom |
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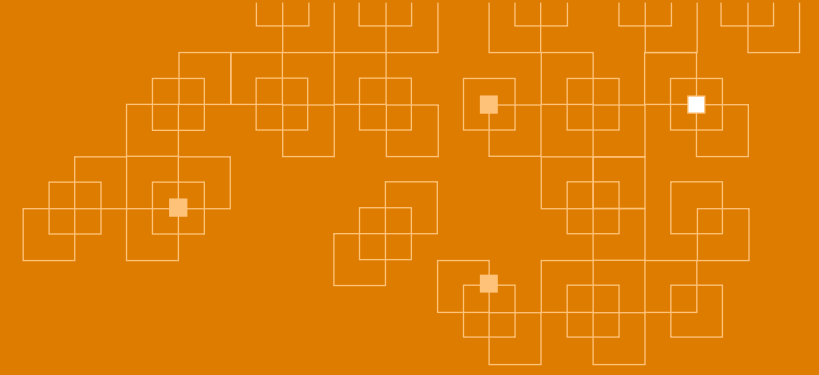
# Panel Discussion

## Panelists:

- Arun Sanyal, Virginia Commonwealth University
- Meena Bansal, Mount Sinai Hospital, NY
- Sven Francque\*, University of Antwerp, Belgium
- George Makar\*, US Food and Drug Administration (FDA)
- Joachim Musaus, European Medicines Agency (EMA)
- Don Chalfin, Patient
- Henry Chang\*, Fatty Liver Foundation
- Michelle Long, NovoNordisk
- Judith Ertle, Boehringer Ingelheim



# General Discussion



# Session III: Advances in Digital Pathology & AI/ML for MASH

**Moderator: *Arun Sanyal, Virginia Commonwealth***



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# The Role of AI/ML in MASH Digital Pathology

*Dean Tai, HistoIndex*



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# The Role of AI/ML in MASH Digital Pathology

*Janani Iyer & Katy Wack\*, PathAI*



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# The Role of AI/ML in MASH Digital Pathology

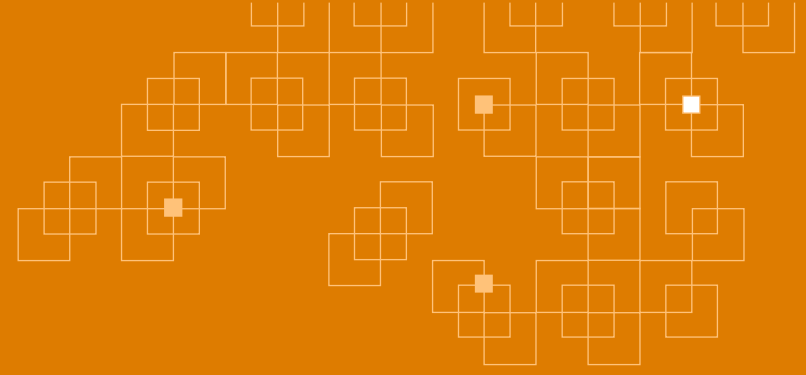
*Mathieu Petitjean, PharmaNest*



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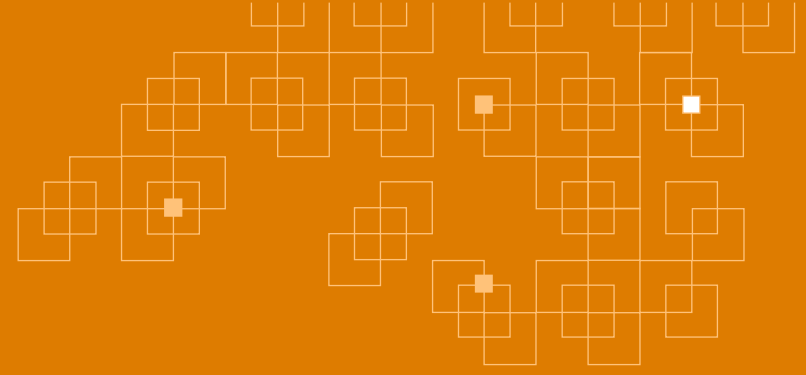
# The Role of AI/ML in MASH Digital Pathology

*Cindy Serdjebi, BioCellvia*



# General Discussion





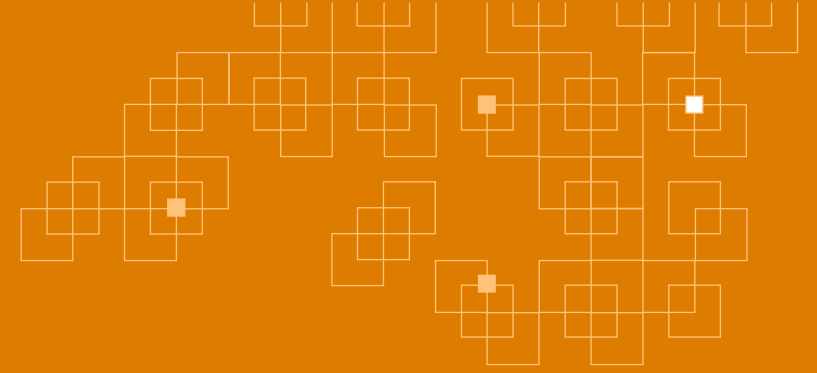
# Coffee Break

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# Session IV: Moving Forward with NITs

## **Moderators:**

***Laurent Castera, Université Paris Cite Hôpital Beaujon***

***Meena Bansal, Mount Sinai Hospital, NY***



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# Brief Overview of Liver Forum Work in NITs

*Veronica Miller, Forum for Collaborative Research*

# COMMENTARIES

## Baseline Parameters in Clinical Trials for Nonalcoholic Steatohepatitis: Recommendations From the Liver Forum



regulatory agencies, the pharmaceutical and medical diagnostics industries, and patient advocacy organizations to develop consensus recommendations for standardized baseline parameters for NASH-related clinical trials.

### Methods

A working group of the Liver Forum assessed the state of the science in clinical trials for NASH and made specific recommendations for the categories of data to

NAFLD fibrosis p morbid condition ular disease.<sup>7</sup> Ag include decrease and mitochondr and ethnicity, oft known genetic considered impc capture for proof phase II trials, an essential compor als. These are t given the curren

Gastroenterology 2017;153:621–625

**Table 1. Metabolic Panel**

|                 | Early Phase Trials | Late Phase Trials |
|-----------------|--------------------|-------------------|
| Fasting glucose | E                  | E                 |
| Fasting insulin | E                  | E                 |
| Hemoglobin A1c  | E                  | E                 |
| HOMA            | C                  | C                 |
| Glucose clamp   | C                  | NR                |
| OGTT            | C                  | C                 |

C, consider; E, essential; HOMA, homeostasis model assessment; NR, not recommended; OGTT, oral glucose tolerance test.

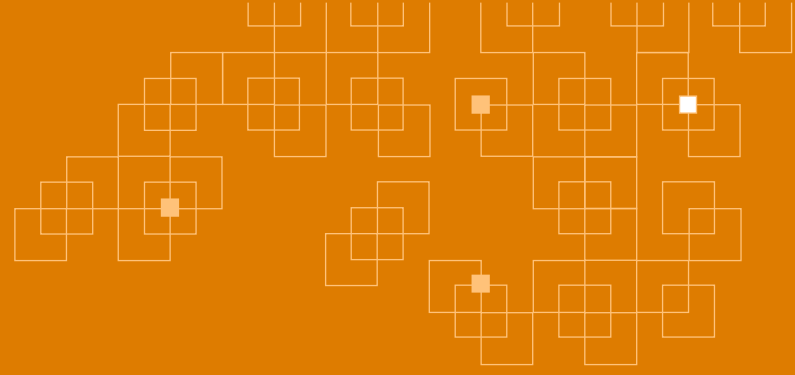
**Table 2. Laboratory Tests**

|                         | Early Phase Trials | Late Phase Trials |
|-------------------------|--------------------|-------------------|
| ALT                     | E                  | E                 |
| AST                     | E                  | E                 |
| ALP                     | E                  | E                 |
| Total bilirubin         | E                  | E                 |
| Direct bilirubin        | E                  | E                 |
| GGT                     | E                  | E                 |
| Albumin                 | E                  | E                 |
| Prothrombin time or INR | E                  | E                 |
| Total cholesterol       | E                  | E                 |
| LDL-C                   | E                  | E                 |
| HDL-C                   | E                  | E                 |
| TSH                     | E                  | E                 |
| Triglycerides           | E                  | E                 |
| Hemoglobin              | E                  | E                 |
| Hematocrit              | E                  | E                 |
| Platelets               | E                  | E                 |
| BUN                     | E                  | E                 |
| Creatinine              | E                  | E                 |
| Urine microalbumin      | C                  | C                 |
| Ferritin                | I                  | I                 |

## Supplementary Materials

- Comorbidities & Surgical History
- Anthropometrics
- Specialized Biomarkers
- Health Related Quality of Life

- LF12
  - Review diagnostic and prognostic NITs
- LF14
  - Review treatment response NITs



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# FDA NIT Workshop: Open Invitation

*Abbas Bandukwala\*, US Food and Drug Administration*



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# Proposal to the Liver Forum

*Quentin Anstee\*, Newcastle University*



# Meta-Thoughts on Response Biomarkers in NASH Drug Development



1. Rapidly attaining a NIT 'response threshold' is not a guarantee of early efficacy.

2. Interpret changes in 'Simple Panels' (APRI, FIB4, NFS) with caution.

**3. In the absence of a single 'gold standard' biomarker, undertake a wholistic assessment of biomarker response and demonstrate change *at the patient level*.**

**4. We should agree and define a common set of biomarkers that will be measured *and reported* in all future clinical trials.**

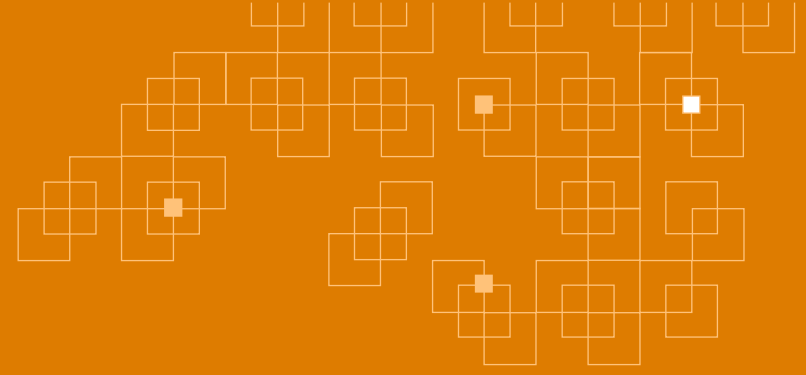
Quentin Anstee LF12

| Trial Phase                          |           | Phase IIa/IIb |            |                        |                 |                   |                         |                      |                         |                             |          |                     |                       |                         |                           |                         |                           |            |                        |                   |             |           |             |            |               |
|--------------------------------------|-----------|---------------|------------|------------------------|-----------------|-------------------|-------------------------|----------------------|-------------------------|-----------------------------|----------|---------------------|-----------------------|-------------------------|---------------------------|-------------------------|---------------------------|------------|------------------------|-------------------|-------------|-----------|-------------|------------|---------------|
| Year                                 |           | 2018          | 2020       | 2021                   | 2021            | 2022              | 2019                    | 2019                 | 2021                    | 2021                        | 2020     | 2020                | 2021                  | 2021                    | 2022                      | 2020                    | 2016                      | 2020       | 2020                   | 2021              | 2015        | 2020      | 2021        | 2018       | 2020          |
| Duration                             |           | 12            | 12         | 12                     | 12              | 12                | 12/36                   | 16                   | 16                      | 16                          | 24       | 24                  | 24                    | 24                      | 24/48                     | 48                      | 52                        | 52         | 52                     | 52                | 72          | 72        | 72          | 96         | 104           |
|                                      |           | Aldafermin    | Aldafermin | TVB-2640 (FASCINATE 1) | Tern-101 (LIFT) | EDP-305 (ARGON-1) | Resmetrom (MGL-3196-05) | Pegbelfermin (FGF21) | Efruxifermin (BALANCED) | Saroglitazar (EVIDENCES IV) | Clofoxor | Combination (ATLAS) | Lanifibranor (NATIVE) | Aldafermin (ALPINE 2/3) | Pegbelfermin (FALCON 1/2) | Tropifexor (FLIGHT-FXR) | Elaftibranor (GOLDEN-505) | Seladelpar | MSDC-0602K (EMMINENCE) | Aramchol (ARREST) | OCA (FLINT) | Emricasin | Semaglutide | Simtuzumab | CVC (CENTAUR) |
| Clinical Chemistry                   | ALT & AST | ✓             | ✓          | ✓                      | ✓               | ✓                 | ✓                       | ✓                    | ✓                       | ✓                           | ✓        | ✓                   | ✓                     | ✓                       | ✓                         | ✓                       | ✓                         | ✓          | ✓                      | ✓                 | ✓           | ✓         | ✓           | ✓          | ✓             |
|                                      | APRI      |               |            |                        |                 |                   |                         |                      | ✓                       | ✓                           |          |                     |                       | ✓                       |                           |                         |                           | ✓          |                        |                   |             |           |             |            | ✓             |
| Simple Scores<br>Indirect Biomarkers | NFS       |               |            |                        |                 | ✓                 |                         |                      |                         |                             |          |                     |                       | ✓                       |                           |                         |                           |            | ✓                      |                   |             |           |             | ✓          |               |
|                                      | FIB4      |               |            |                        |                 | ✓                 |                         |                      |                         | ✓                           |          | ✓                   |                       | ✓                       |                           |                         |                           |            | ✓                      | ✓                 |             |           |             |            | ✓             |
|                                      | CK18      |               |            | ✓                      |                 |                   | ✓                       |                      | ✓                       | ✓                           | ✓        | ✓                   |                       |                         |                           |                         |                           | ✓          | ✓                      |                   |             | ✓         | ✓           |            |               |
|                                      | ELF       | ✓             | ✓          | ?                      |                 |                   | ✓                       |                      | ✓                       | ✓                           | ✓        | ✓                   | ✓                     | ✓                       | ✓                         |                         |                           |            | ✓                      | ✓                 |             |           |             | ✓          | ✓             |
| Direct Biomarkers                    | Fibrotest |               |            |                        |                 |                   |                         |                      |                         | ✓                           |          |                     |                       |                         |                           |                         | ✓                         |            | ✓                      |                   |             |           |             | ✓          |               |
|                                      | PRO-C3    | ✓             | ✓          | ✓                      |                 |                   | ✓                       | ✓                    | ✓                       |                             |          |                     | ✓                     | ✓                       | ✓                         |                         |                           |            |                        |                   |             |           |             |            | ✓             |
|                                      | VCTE      |               |            |                        |                 |                   |                         |                      | ✓                       | ✓                           | ✓        | ✓                   |                       |                         | ✓                         |                         |                           |            |                        |                   |             |           |             | ✓          |               |
| Fibroscan                            | FAST      |               |            |                        |                 |                   |                         |                      |                         |                             | ✓        |                     |                       |                         |                           |                         |                           |            |                        |                   |             |           | ✓           |            |               |
|                                      | MR-PDFF   | ✓             | ✓          | ✓                      | ✓               | ✓                 | ✓                       | ✓                    | ✓                       | ✓                           | ✓        | ✓                   |                       | ✓                       | ✓                         | ✓                       |                           | ✓          |                        | ✓                 |             |           |             |            |               |
| MR                                   | MR-ct1    |               | ✓          |                        | ✓               |                   |                         |                      |                         |                             |          |                     |                       |                         |                           |                         |                           |            |                        |                   |             |           |             |            |               |
|                                      | MRE       |               |            |                        |                 |                   |                         | ✓                    |                         |                             | ✓        | ✓                   |                       |                         | ✓                         |                         |                           |            |                        |                   |             |           |             |            |               |
| Liver Biopsy                         | Histology |               | ✓          | ✓                      |                 |                   | ✓                       |                      | ✓                       |                             |          |                     | ✓                     | ✓                       | ✓                         | ✓                       | ✓                         | ✓          | ✓                      | ✓                 | ✓           | ✓         | ✓           | ✓          | ✓             |

# Panel Discussion

## Panelists:

- Manal Abdelmalek\*, Mayo Clinic
- Vlad Ratziu, Sorbonne Université
- Claudia Filozof, Fortrea
- Corinna Schoelch, Boehringer Ingelheim
- Michael Betel, Fatty Liver Alliance
- Michael Middleton, UC San Diego



# Session V: Stretch Exercise: Pragmatic Benefit-Risk Assessment for Diagnostics

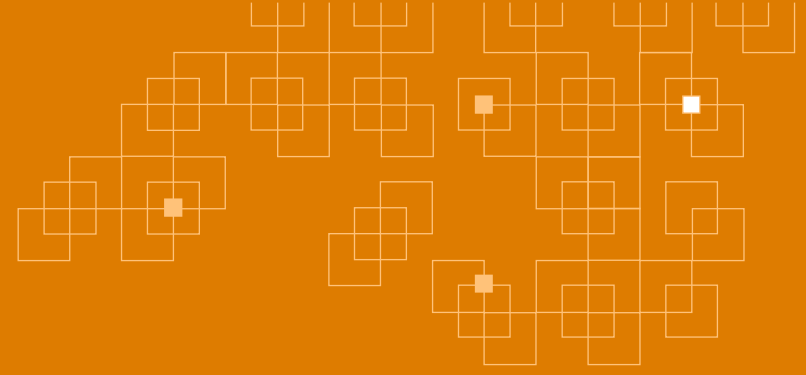
**Moderator: *Veronica Miller, Forum for Collaborative Research***



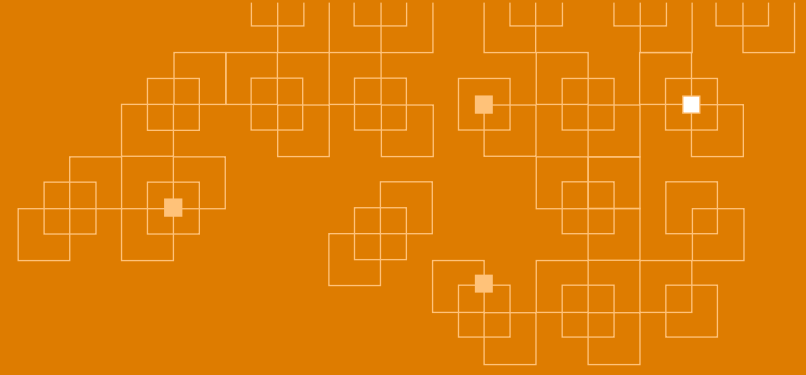
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# A New Look at Benefit-Risk in Diagnostics

*Scott Evans, George Washington University*



# General Discussion



# Session VI: Working Group Updates and Proposals

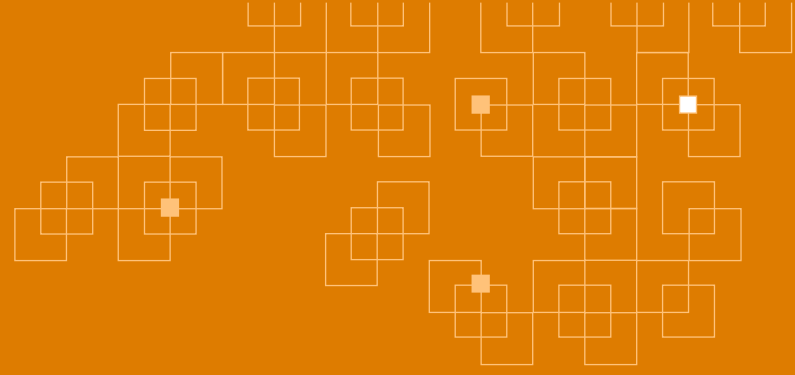


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# MASH (NASH) Placebo Arm Database

**Michael Cooreman**, *Inventiva Pharma*

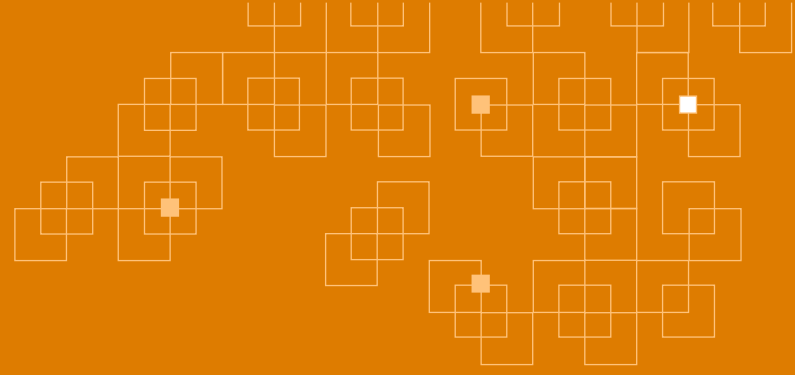




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# Combination Therapy

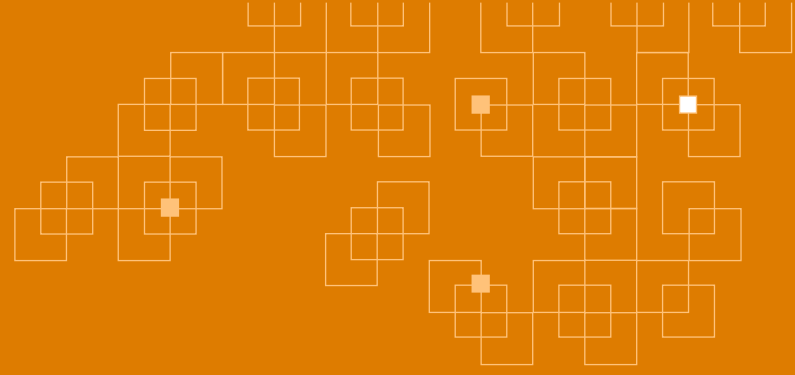
*Michelle Long, Novo Nordisk*



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# Pooling of Endpoints Across Trials

*Michelle Long, Novo Nordisk*



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# Discussant

*Laurent Castera, Université Paris Cite Hôpital Beaujon*



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# New Working Group: Radiology Liver Diseases (RLD) Program

*Michael Middleton, UC San Diego*



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# New Working Group: Intersection of Steatotic Liver Disease (SLD) and Alcohol Liver Disease (ALD)- Met-ALD

*Nikhil Vergis, GlaxoSmithKline*

**Berkeley** Public  
Health

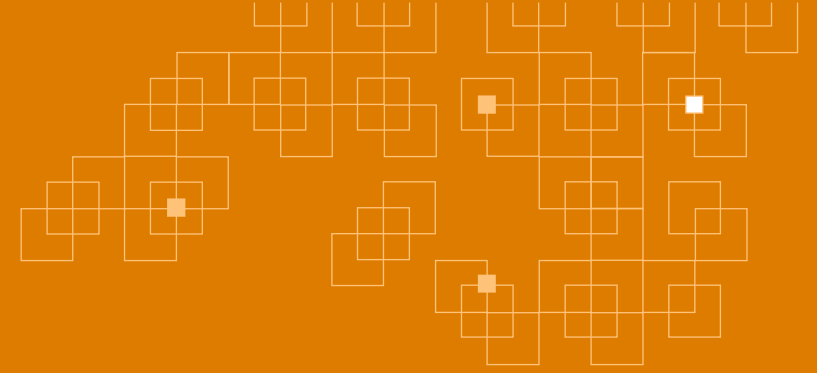


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# Discussants

*Donna Cryer, Global Liver Institute*

*Roberto Calle\*, Regeneron*



# Closing Remarks

- ***Arun Sanyal, Virginia Commonwealth University***
- ***Judith Ertle, Boehringer Ingelheim***
- ***Veronica Miller, Forum for Collaborative Research***

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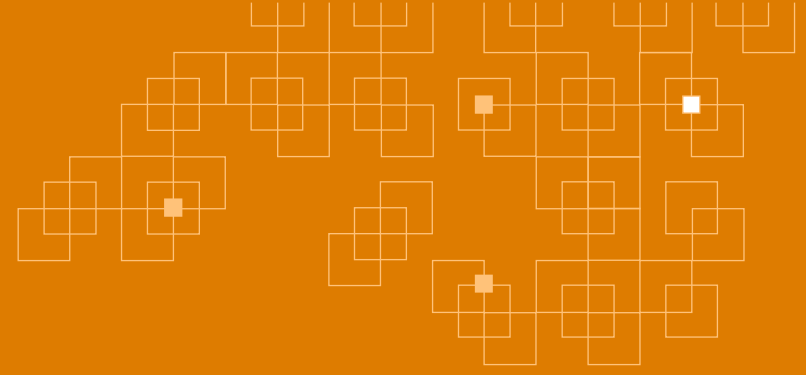
EA Pharma Co., Ltd.





# LF 15 Evaluation & Working Groups Sign up

- Use the QR codes provided for you in your participant folder to complete the evaluation and sign up for the new working groups



# Adjourn and Networking Reception