



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

# Radiology Liver Disease (RLD) Program

**Liver Forum 16**  
**In-Person and Virtual Annual Meeting**  
**March 22, 2024**  
**Session III**  
**Collaboration for Greater Efficiency**

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# Disclosures (Middleton)



<b>Consultation:</b>	Alimentiv, Arrowhead, AutonomUS, Glympse, Kowa, Livivos, Median, Novo Nordisk
<b>Lab service agreements:</b>	Alexion, AstraZeneca, Bristol-Myers Squibb, Celgene, Enanta, Galmed, Genzyme, Gilead, Guerbet, Intercept, Ionis, Janssen, NuSirt, OrsoBio, Organovo, Pfizer, Roche, Sanofi, Shire, Synageva, Takeda
<b>Stockholder:</b>	Pfizer AutonomUS ( <i>stock options</i> ) Livivos ( <i>pending stock options</i> )
<b>Co-founder:</b>	Quantix Bio

# Disclosures (Sirlin)



- Non-federal grant support:** ACR, Bayer, Foundation of NIH, GE, Gilead, Pfizer, Philips, Siemens, V Foundation
- Personal consultation:** Altimmune, Ascelia Pharma, Blade, Boehringer, Epigenomics, Guerbet, Livivos
- Institutional consultation:** BMS, Exact Sciences, IBM-Watson, Pfizer
- Lab service agreements:** OrsoBio, Enanta, Gilead, ICON, Intercept, Nusirt, Shire, Synageva, Takeda
- Stockholder:** Livivos
- Executive position:** Livivos (Chief Medical Officer, through June 28, 2023)

# Membership (37)



▪ **Chair:** Michael Middleton, UCSD

▪ **Co-Chair:** Claude Sirlin, UCSD

▪ **Members:** Abbas Bandukwala, FDA  
Mustafa Bashir, Duke  
Laurent Castera, U Paris Cité  
Elaine Chng, HistoIndex  
Jonathan Dillman, Cleveland Children's  
Richard Ehman, Mayo Clinic  
Ahmed El Kaffas, UCSD  
Michael Fuchs, VCU  
Aiguo Han, Virginia Tech  
Stefanie Hectors, Regeneron  
Harry Hu, U Colorado  
Mike Kalutkiewicz, Resoundant  
Azza Karrar, Forum  
Sehyr Khan, Forum  
Veronica Miller, Forum  
Philip Newsome, Birmingham  
Michael Ohliger, UCSF  
Kay Pepin, Resoundant

Perry Pickhardt, U Wisconsin  
Theodore Pierce, Harvard  
Pablo Prado, Livivos  
Scott B Reeder, U Wisconsin  
Matthew Robson, Perspectum  
Cindy Serdjebi, Biocellvia  
Sarah Sherlock, Pfizer  
Andrew Smith, U Alabama  
Dean Tai, Histoindex  
An Tang, Université de Montréal  
Sudhakar Venkatesh, Mayo Clinic  
Andrew Trout, Cleveland Children's  
Katy Wack, PathAI  
Margot Yan, Forum  
Benjamin Yeh UCSF  
Meng Yin, Mayo Clinic  
Takeshi Yokoo, U Southwestern

# Membership



- **Academic: 22** *Birmingham, Cleveland Children’s (2), Duke, Harvard, Mayo Clinic (3), U Alabama, U Colorado, U Paris Cité, Université de Montréal, U Southwestern, U Wisconsin (2), UCSD (3), UCSF (2), VCU, Virginia Tech*
- **Industry: 10** *Biocellvia, HistoIndex (2), Livivos, PathAI, Perspective, Pfizer, Regeneron, Resoundant (2)*
- **FDA: 1**
- **Forum: 4**

# Membership

- ***Current expertise***

*Quantitative CT  
Quantitative MRI  
Quantitative US  
Quantitative Histology  
Hepatology  
Technology development*

- ***Additional expertise?***

*Pathology  
Biostatistics*

*Members include  
**inventors and pioneers**  
of key technologies*



# RLD History

- ***Founded:*** *August 18, 2023*
- ***Meetings:*** *February 25, 2024 (virtual)*  
*March 15, 2024 (virtual)*



# Unprecedented opportunity

**To advance radiological study of liver disease**

## **Current status of radiology studies**

- *Small*
- *Radiology-centered*
- *Single- or oligo-biomarker*
- *Single- or oligo-center*
- *Single- or oligo-vendor*
- *Often highly enriched*
- *Often retrospective*
- *Often cross-sectional only*



## **Opportunity:**

- *Large*
- *Patient-centered*
- *Single- or oligo-biomarker*
- *Multi-center*
- *Multi-vendor*
- *Generalizable to target populations*
- *Prospective*
- *Multi-time point, longitudinal*



# Mission and Vision Statements



- **Mission:** To provide broad, relevant, and diverse radiology expertise to the Liver Forum
- **Vision:** To accelerate the development of diagnostics and therapeutics in liver disease by supporting the integration of quantitative imaging biomarkers in clinical care and clinical trials including the development of infrastructure to inform and assist those efforts

# Scope



- **Initial focus:** *Diagnosis and monitoring of MASLD  
Clinical trials and clinical research*
- **Future:** *Other contexts of use  
Other chronic liver diseases (e.g., PSC)  
Liver cancer  
Clinical care*

# Charge of RLD Leadership



- Foster open, fair, transparent, collaborative, flexible, inclusive, and diverse environment
- Leverage infrastructure and expertise of the entire Liver Forum
- Leverage expertise of RLD Program
- Lead and coordinate RLD Working Groups
- Target projects that are **complementary** to Liver Forum Groups or groups outside the Liver Forum (i.e., NASH CRN, LCN, LITMUS, NIMBLE, ACR, Scientific Societies, etc.)
- Promote career development and mentorship
- Report progress at Liver Forum meetings

# Projects



- **Proposed initial projects**

- **Data Repository** – create and maintain biomarker repository, imaging repository
- **Standardization of Data Acquisition, Quality Control, and Analysis for Clinical Trials and Cohort Studies** - create standardized Procedure Manuals and Charters
- **Ad hoc** – respond to requests from industry, FDA, Liver Forum, other Liver Forum Programs (i.e., PSC, Placebo, etc.)

# Working Groups



- **Proposed initial working groups**

- **Data Repository Working Group** - biomarker repository, imaging repository
- **Data Acquisition, Quality Control, and Analysis Working Group** - create standardized Procedure Manuals and Charters
- **Ad hoc groups** – formed as needed to address requests from industry, FDA, Liver Forum, other Liver Forum Programs (i.e., PSC, Placebo, etc.)

# Working Groups



- **Future working groups?**
  - **COU Working Group(s)** - i.e., Diagnostic Enrichment, Treatment Response, etc.
  - **Disease-focused Working Group(s)** - i.e., MASLD, PSC, Liver Cancer
  - **AI Working Group(s)** – for validation of models
  - **Radiology/Pathology Working Group** - include industry and pathologists
  - **Radiology/Regulatory Working Group** - to continue on from the 9/18/23 FDA meeting; liaison with Biomarker Qualification Program (BQP)
  - **Pediatrics Working Group**

# Next steps



- **Convene the two proposed RLD working groups**
  - *obtain approval from, and plan cooperation with Liver Forum*
  - *assign leadership*
  - *develop charges, 1 and 3 year timelines, and deliverables*

## ***Questions / Discussion***

***Thank you***

**Contact information:**

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