Liver Matters

Observational Research Capabilities in Liver

pulse infoframe™

Liver MATTERS®

October 2024


uncompromised quality
Agile, efficient evidence generation with a technology-first approach
less resources

We specialize in observational research.

- ✓ We bring the best team to the table for every sponsor
- ✓ Data in our platform have been used with regulators, including the FDA and EMA
- ✓ We have run everything from Natural History Studies to Post-Marketing Safety Studies
- ✓ We have worked with big pharma and biotechs
- ✓ >10 year track record

Our bold vision for Liver MATTERS™

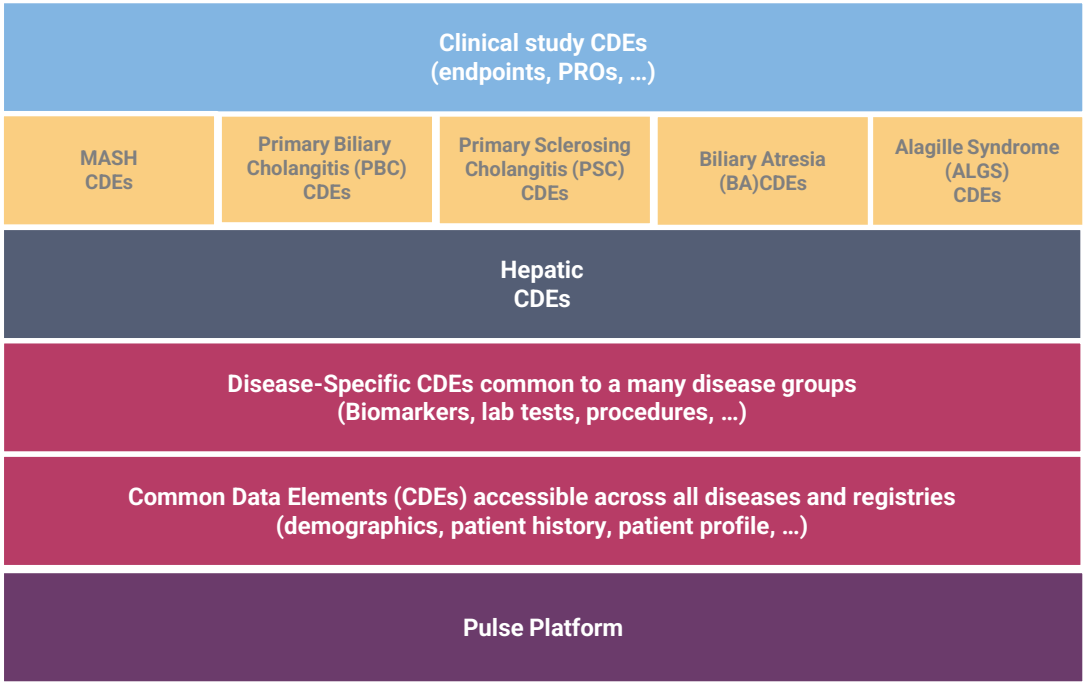
Revolutionize liver research using regulatory-grade* real-world data

We are intent on pushing the frontiers of liver research across rare and chronic liver diseases by bringing together a pre-competitive consortium of pharma collaborators to create a geographically diverse liver-focused registry across North America and Europe.

** The Pulse platform meets all current privacy requirements, including HIPAA, GDPR, SOC 2 Type 2, 21 CFR 11, and ISO27001 certification*

Enable RWD collection in multiple diseases of interest across your pipeline

- The Pulse platform has been utilized with a large global pharma to assess pruritis associated with PBC in the US and Germany.
- With an established platform and set of common data elements established, **Pulse is seeking pharma sponsors to support the work across liver disease, globally.**



A robust foundation of real-world data

By launching with ePROs and providing optionality to expand clinical, phenotypic and biomarker data, we offer sponsors a pragmatic platform to augment research, understanding of disease, clinical trial performance, and treatment effectiveness.

- Decentralized model
- Hepatic Common Data Elements (CDEs) across conditions
- Disease-specific Data Elements, incl. PBC and MASH
- Omics Data
- Social Listening
- Sub-studies
- Site expansion (eCOAs, eCRFs)

**Registry design at launch to be finalized based on confirmed number of sponsors and launch sponsor priorities.*

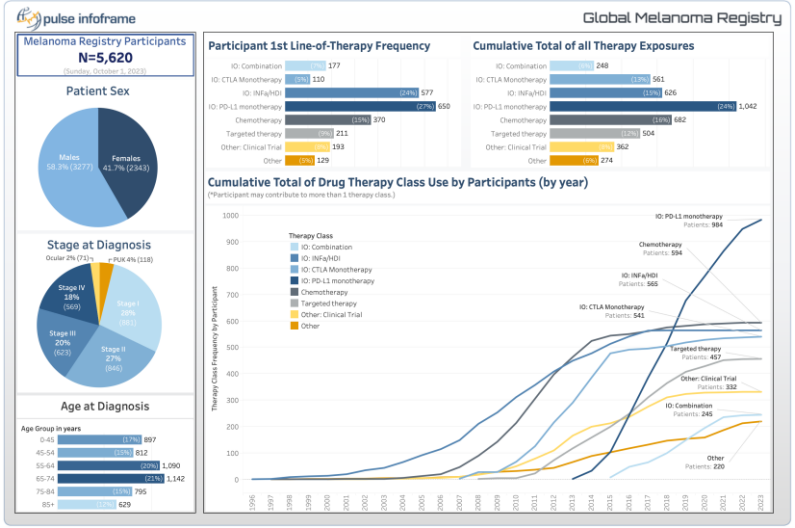
Flexible data access model

Pre-set aggregate data access packages to support multi-year evidence work, each including various data access options described below.

1. Dashboards
   - Continuously available descriptive displays of real-time data
2. Reports
   - Pulse biostatisticians develop and run analytics that fulfill specific research questions and time requirements
3. Publications
   - Pulse has proven and exceptional medical writing capabilities for abstracts and support with manuscripts.

...and more

- Consortium sponsors may fund custom sub-studies and additional data access.



Note: Example dashboard from Pulse's global melanoma registry.

 www.pulseinfoframe.com

Sub-study ready

Configuration is part of our DNA. To support sub-studies of interest to sponsors, the Pulse platform has been natively built to be configured with ease with the depth of study workflow required by sponsors.

- Tailor look and feel for the sub-study
- Collect additional data elements (ePROs, eCOAs, and eCRFs)
- Add consent or assent workflows, including pediatric/caregiver workflows
- Ingest and harmonize retrospective data
- Add and manage file uploads
- Clinically validate patient-reported data remotely
- Configure Adverse Event Triggers/Notifications
- Integrate real-world and randomize control trial data via advanced modeling and AI/ML

We enable evidence generation throughout the lifecycle of a molecule

Pre-Clinical

- Natural history data
- Deepen relationships with expert researchers
- Inform pipeline prioritization

Early Clinical

- Inform trial design
- Develop clinical endpoints
- Define and create comparator arms

Late Clinical and Post-Approval

- Capture QoL data
- External control arms
- Market Access studies
- Reimbursement & Payor evidence
- Long-Term Follow-Up
- Safety and REMS studies