pulse infoframe™

high quality data & analysis

Agile, efficient real-world research with a technology-first approach

with less time, labor & costs

Case Studies & Publications

March 2025

Pulse Infoframe is a global healthcare company that has developed a best-in-class real-world evidence platform to build registries, conduct natural history studies, and support safety studies for more than a decade.

Pulse's cloud-based platform enables the collection of real-world data from patients and clinicians, the ingestion of existing data from sites, registries and clinical trials, and streamlines analyses of those data.

By adhering to best practices in data standards and storage, Pulse unlocks the full value of real-world evidence across the product lifecycle, helping drive more informed internal decisions throughout clinical development, support regulatory submissions, and enhance pricing and reimbursement discussions with payers.

Important Things to Know About pulse infoframe

Differentiation	>10 years exclusive focus on real-world research	Technology-first approach to collect, harmonize, and analyze RWD with less time/labor/cost			
End-to-End Capabilities	Data Collection (Patient ePROs & Clinician eCRFs)	Data Ingestion	Evidence Generation (Reports, Dashboards, Bring-Your-Own-Analytics)		
Experience	Registries	Natural History	External Comparators	Safety	Market Access
Data Quality	GDPR-compliant (80+ countries)	SOC 2 certified (MSAs with top 10 pharma)	Regulatory-grade data (FDA-ready CDISC format)		

Pulse RWE Use Cases

Registries

- Collect longitudinal data
- Improve patient recruitment for trials

Natural History

- Inform trial design
- Select endpoints
- Identify biomarkers

External Comparators

- Run efficient, lower cost pivotal trials
- Enhance FDA package

Safety

- Fulfill post-marketing requirements
- Run efficient Long-Term Follow-Up studies

Market Access

- Inform decisions around pricing and reimbursement
- Enhance knowledge sharing and scientific credibility

Enhances internal decision-making	Enhances regulatory decision-making	Enhances payer decision-making

Case Studies

Case Study:
PBC Feasibility Assessment

Patient-Centric Study Design for PBC Findings from a Pulse Feasibility Assessment

Project Context

- Non-interventional ambispective study focusing on adult Primary Biliary Cholangitis (PBC) patients with recent-onset pruritus
- Aim: Examine real-world treatment experiences and impact of pruritus on quality of life
- Rare and complex disease requiring data from multiple healthcare systems
- Need for patient-reported outcomes (PROs) to link clinical outcomes with patient experiences
- Barriers to recruitment: cultural, logistical, regional care differences, and digital literacy levels
- Importance of patient engagement and accessibility to ensure meaningful data collection

The solution

- Extensive interviews with advocacy groups, clinicians, and patients to gather insights
- Identified the need for customized language translations and community engagement strategies
- Developed a patient-centric study design emphasizing patient empowerment and engagement
- Designed for both centralized and decentralized recruitment models to maximize participation flexibility
- Integrated patient-reported data with clinical data to provide a holistic view of patient experiences

The results

- Built a patient-centric registry infrastructure to support future PBC research
- Enabled a decentralized, flexible recruitment model while enhancing patient accessibility and engagement
- Demonstrated Pulse's expertise in designing inclusive, patient-driven research models for rare diseases

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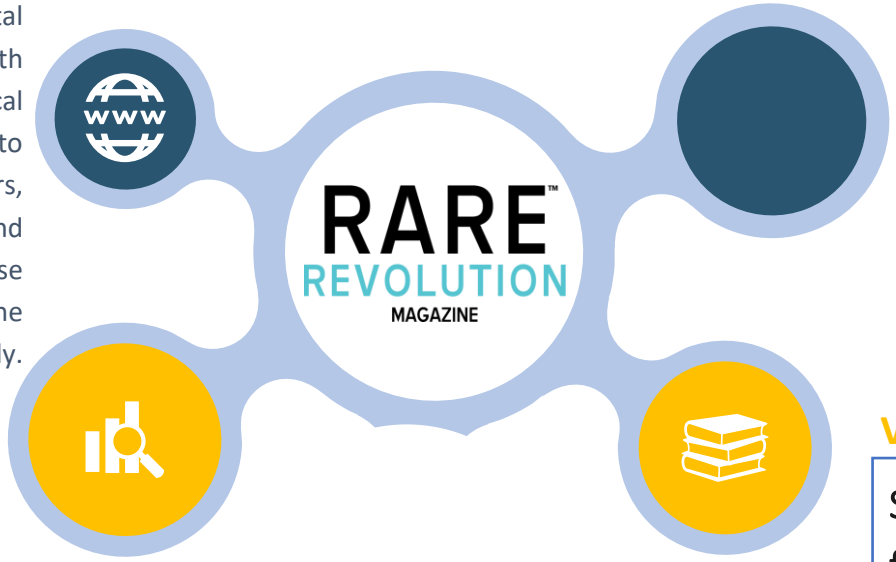
PBC Digital Spotlight

Case Study

Approach

RARE Revolution produced a digital spotlight in collaboration with Pulse, with financial support from pharmaceutical company. Working closely with Pulse to secure the participation of contributors, RARE Revolution conducted interviews and wrote four of the five articles. Pulse Infoframe wrote the fifth article, about the pharma-sponsored PBC study.



Expansion

This digital spotlight was launched on 16th December 2023 and was promoted by both Pulse Infoframe and Rare Revolution through coordinated campaigns

Goals

- Increase understanding of PBC
- Elevate the community's voice
- Understand lived experiences to highlight unmet needs.

View the Full Spotlight

See the all five articles from the PBC digital spotlight here

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Case Study:
Hybrid Registry – 1 of 2

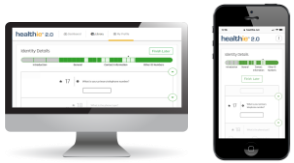
Pulse delivers a highly configurable user experience to collect RWD and generate RWE in one single platform

Real-World Data Collection → **Real-World Evidence Generation**

Feasibility & Design

Patient or site completes pre-screen

If eligible, patient creates account and signs eConsent



Patient completes ePROs and/or site completes eCRFs

Sponsor accesses regulatory-grade data

RWE insights have informed expansion of **RWD collection** (patient-facing arm, proposed new indications, etc.)

Tech

- ✓ Look and feel
- ✓ Consent flow
- ✓ Adverse Event (AE) triggers
- ✓ Form validations
- ✓ Separation of PII
- ✓ Patient portal
- ✓ eConsent
- ✓ Proxy/caregiver workflows
- ✓ ePROs / eCRFs / eCOAs
- ✓ Smart scheduled reminders
- ✓ 3rd party data ingestion (Data Transfer Agreement to ingest retrospective data from prior registry)

Services

- ✓ PI Meetings
- ✓ Protocol/IRB
- ✓ Data Dictionary
- ✓ Governance
- ✓ Site onboarding and contracting
- ✓ Tech-enabled ClinOps
- ✓ Patient engagement
- ✓ Data extraction from uploaded files
- ✓ Biostat reports
- ✓ Medical writing

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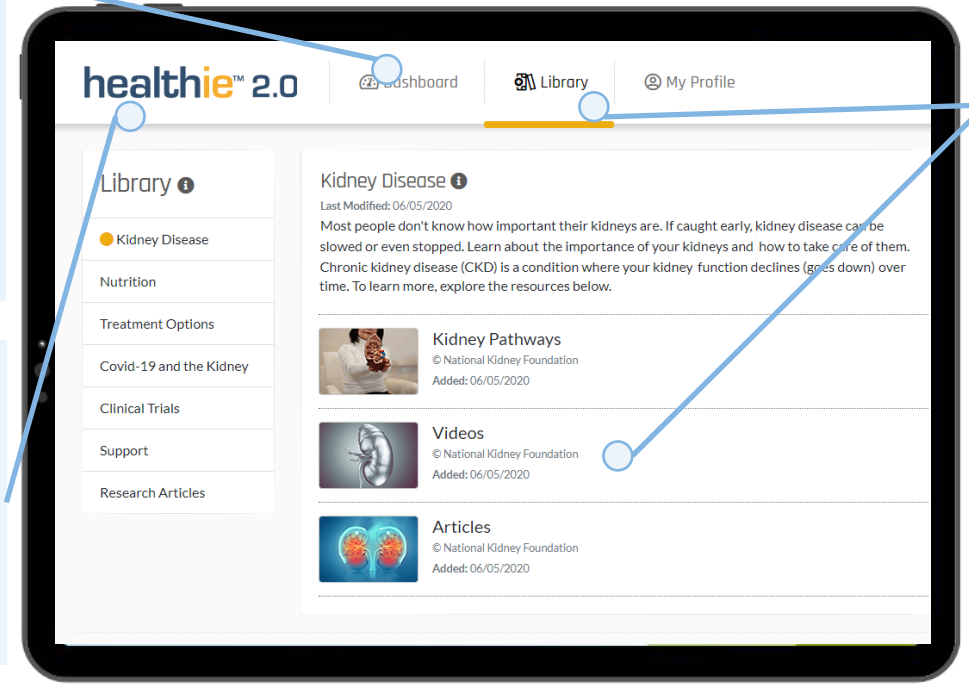
Case Study:
Hybrid Registry – 2 of 2

Pulse's patient portal drives patient engagement

Patient dashboard:
- ✓ Aggregate data views (map, demographics, etc.)
- ✓ Builds sense of community
- ✓ Shows the value of data being collected
- ✓ Patients can see data they entered but not clinical data added by sites

Global platform translated into 26+ languages (*excludes PROs*)
- ✓ Includes emails & texts
- ✓ Colloquial & modern
- ✓ 5th grade reading level
- ✓ Right-to-left
- ✓ Cyrillic and Symbols
- ✓ Mandarin, Japanese, others



Rich library & content
- ✓ Supports full localization
- ✓ Updated as frequently as content is made available

Localized support options - site content can be augmented to include help emails, phone numbers, and issue site notifications about questions a participant might have

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Case Study:
Long-Term Follow-Up

Agile start-up and an efficient, decentralized study design proposed by Pulse and accepted by FDA

Project Context

- 5-year Long-Term Follow-Up study
- FDA-mandated
- Ultra-rare disease
- Pediatric patient population
- Broad geographic distribution of patients
- Requirement to capture data both in the home setting and from sites
- Requirement to capture all adverse events (AE) and serious adverse events (SAEs) so that they could be reported

The solution

- Pulse designed and proposed a decentralized study design with remote onboarding and remote data collection (including clinical data and pre-specified laboratory tests)
- The proposed workflow and Pulse-developed protocol was submitted to the FDA within 3 months and accepted
- The platform was then configured with go live within 4 months.

The results

- Minimized patient burden as participants didn't need to transfer care to a traditional clinical research site to participate
- Avoided the inefficiency of opening multiple study sites in advance and waiting for a new incident patient to be diagnosed or referred for medical care

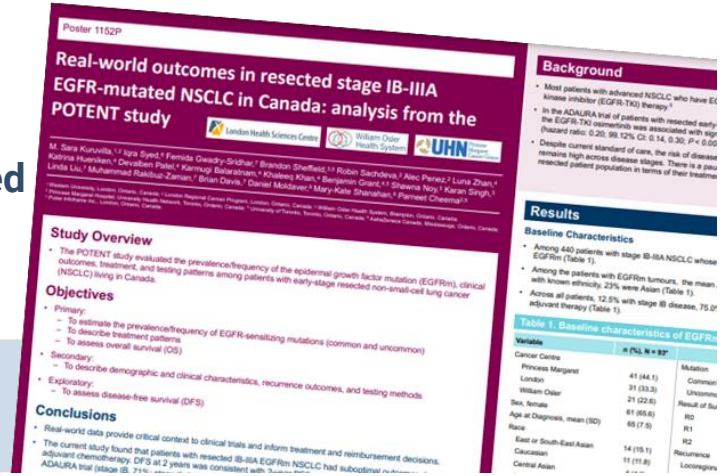
Case Study:

Phase IV pricing & reimbursement support

Real world outcomes in resected stage IB-IIIA EGFR mutated NSCLC in Canada: Analysis from the POTENT study

M. Sara Kuruvilla1,2, Iqra Syed, Femida Gwadry-Sridhar, Brandon Sheffield, Robin Sachdeva, Alec Pencz, Luna Zhan, Katrina Hueniken, Devalben Patel, …, Parneet Cheema

Conclusions: Real world data provide critical context to clinical trials and inform treatment and reimbursement decisions. Pts with resected IB-IIIA EGFRm NSCLC had suboptimal outcomes, despite adjuvant chemotherapy.


Poster 1152P

Real-world outcomes in resected stage IB-IIIA EGFR-mutated NSCLC in Canada: analysis from the POTENT study

London Health Sciences Centre · William Osler Health System · UHN

M. Sara Kuruvilla,[1,2] Iqra Syed,[2] Femida Gwadry-Sridhar,[2] Brandon Sheffield,[2,3] Robin Sachdeva,[2] Alec Pencz,[2] Luna Zhan,[4] Katrina Hueniken,[4] Devalben Patel,[4] Karmugi Balaratnam,[4] Khaleeq Khan,[4] Benjamin Grant,[4,5] Shawna Nixy,[4] Karan Singh,[5] Linda Liu,[5] Muhammad Rakibul-Zaman,[6] Brian Davis,[7] Daniel Moldaver,[8] Mary-Kate Shanahan,[8] Parneet Cheema[2,3]

Study Overview

- The POTENT study evaluated the prevalence/frequency of the epidermal growth factor mutation (EGFRm), clinical outcomes, treatment, and testing patterns among patients with early-stage resected non-small-cell lung cancer (NSCLC) living in Canada.

Objectives

- Primary:
  - To estimate the prevalence/frequency of EGFR-sensitizing mutations (common and uncommon)
  - To describe treatment patterns
  - To assess overall survival (OS)
- Secondary:
  - To describe demographic and clinical characteristics, recurrence outcomes, and testing methods
- Exploratory:
  - To assess disease-free survival (DFS)

Conclusions

- Real-world data provide critical context to clinical trials and inform treatment and reimbursement decisions.
- The current study found that patients with resected IB-IIIA EGFRm NSCLC had suboptimal outcomes, despite adjuvant chemotherapy. DFS at 2 years was consistent with

Background

- Most patients with advanced NSCLC who have E… kinase inhibitor (EGFR-TKI) therapy.[1]
- In the ADAURA trial of patients with resected early… the EGFR-TKI osimertinib was associated with sig… (hazard ratio: 0.20; 96.12% CI: 0.14, 0.30; P< 0.00…
- Despite current standard of care, the risk of disease… remains high across disease stages. There is a pau… resected patient population in terms of their treatme…

Results

Baseline Characteristics

- Among 440 patients with stage IB-IIIA NSCLC whose… EGFRm (Table 1).
- Among the patients with EGFRm tumours, the mean… with known ethnicity, 23% were Asian (Table 1).
- Across all patients, 12.5% with stage IB disease, 75.0… adjuvant therapy (Table 1).

Table 1. Baseline characteristics of EGFR…

Variable	n (%), N = 93*
Cancer Centre	
Princess Margaret	41 (44.1)
London	31 (33.3)
William Osler	21 (22.6)
Sex, female	61 (65.6)
Age at Diagnosis, mean (SD)	65 (7.5)
Race	
East or South-East Asian	14 (15.1)
Caucasian	11 (11.8)
Central Asian	

Mutation
Common
Uncomm…
Result of Su…
R0
R1
R2
Recurrence
Locoregion…

The results

Pulse's RWD identified a considerable unmet need for a large patient population.

- Large registries providing robust cohorts for sub-analysis (e.g., specific mutations)
- Diverse populations including under-represented groups across multiple sites
- Uniform data and disease models, and curation across sites and conditions

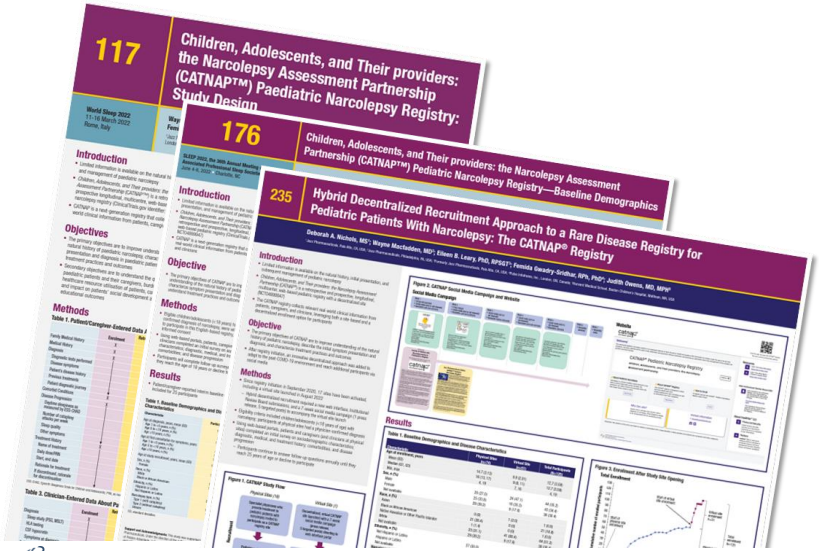
View the Poster

Case Study:

Knowledge Dissemination

Publication readiness and medical writing capabilities

Pulse engages registry sponsors and partners with Scientific Advisory Board members to collaborate on abstracts and posters and has supported numerous publications at major conferences. Through built-in curation, Quality Assurance, and data governance SOPs Pulse enables our data analysis requires less labor due, in part, to quicker evaluation and correction of erroneous data before it makes it to analysis.



- ✓ 5 publications on CATNAP registry design, data, and the decentralized recruitment
- ✓ Knowledge dissemination at global conferences:

World Sleep 2023 Rio de Janeiro Brazil · SLEEP 2023 June 3–7 | Indianapolis, IN · World Sleep 2022 Rome, Italy · SLEEP 2022 · Pediatric Sleep Medicine

- ✓ Rapid data availability to support aggressive timelines

200+ team publications: https://www.pulseinfoframe.com/papers-publications/

Posters: https://www.pulseinfoframe.com/posters/

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Case Study:
Trial Support

Data curation & PROs to support interventional trial

Adjuvant Crizotinib in High-Risk Uveal Melanoma Following Definitive Therapy

Shaheer Khan, Jose Lutzky, Alexander Noor Shoushtari, Joanne M. Jeter, Cody Chiuzan, Naomi Sender, Lauren Esther Blumberg, Alexandra Nesson, Shahnaz V. Singh-Kandah, Susana Hernandez, Grazia Ambrosini, Oliver Surriga, Gary K. Schwartz, Richard D. Carvajal

The use of adjuvant crizotinib in patients with high-risk UM did not reduce rates of relapse in this multicenter, single arm trial. 9/32 (28%) pts required dose modification or discontinuation due to AE which may have limited efficacy.

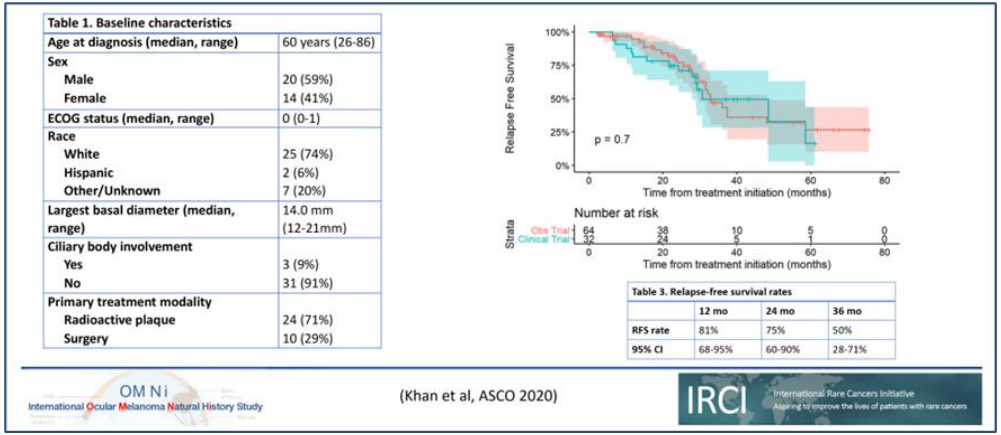

Table 1. Baseline characteristics	
Age at diagnosis (median, range)	60 years (26-86)
Sex	
Male	20 (59%)
Female	14 (41%)
ECOG status (median, range)	0 (0-1)
Race	
White	25 (74%)
Hispanic	2 (6%)
Other/Unknown	7 (20%)
Largest basal diameter (median, range)	14.0 mm (12-21mm)
Ciliary body involvement	
Yes	3 (9%)
No	31 (91%)
Primary treatment modality	
Radioactive plaque	24 (71%)
Surgery	10 (29%)

Table 3. Relapse-free survival rates			
	12 mo	24 mo	36 mo
RFS rate	81%	75%	50%
95% CI	68-95%	60-90%	28-71%

OMNi International Ocular Melanoma Natural History Study

(Khan et al, ASCO 2020)

IRCI International Rare Cancers Initiative

Pulse provided the platform, site and data management, and support for this interventional trial within our broader Uveal Melanoma registry

- Existing, established relationships with sites and investigators to facilitate programs
- All data curation and management, investigator dashboards, patient consents and PROs on Pulse Healthie® platform
- Uniform data and disease models, and curation across sites and conditions

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Contact

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