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

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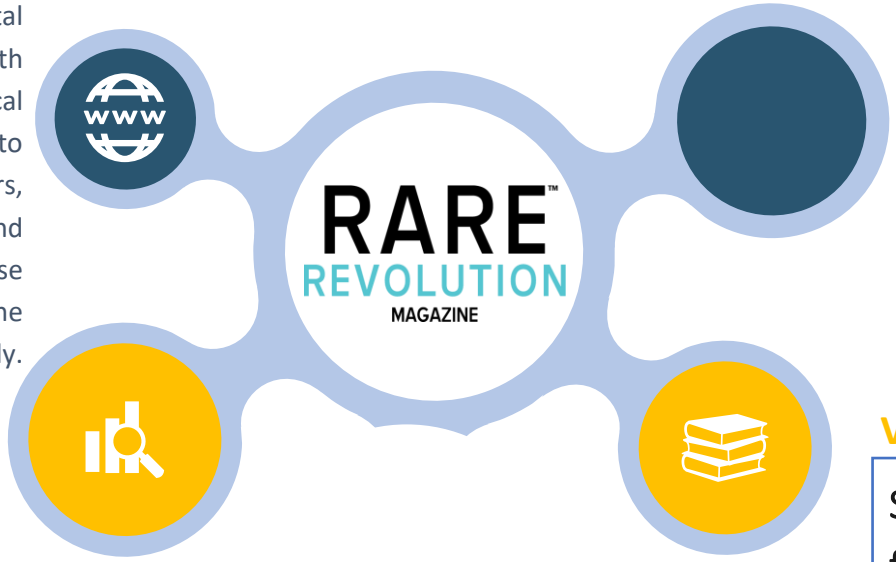
Case Studies

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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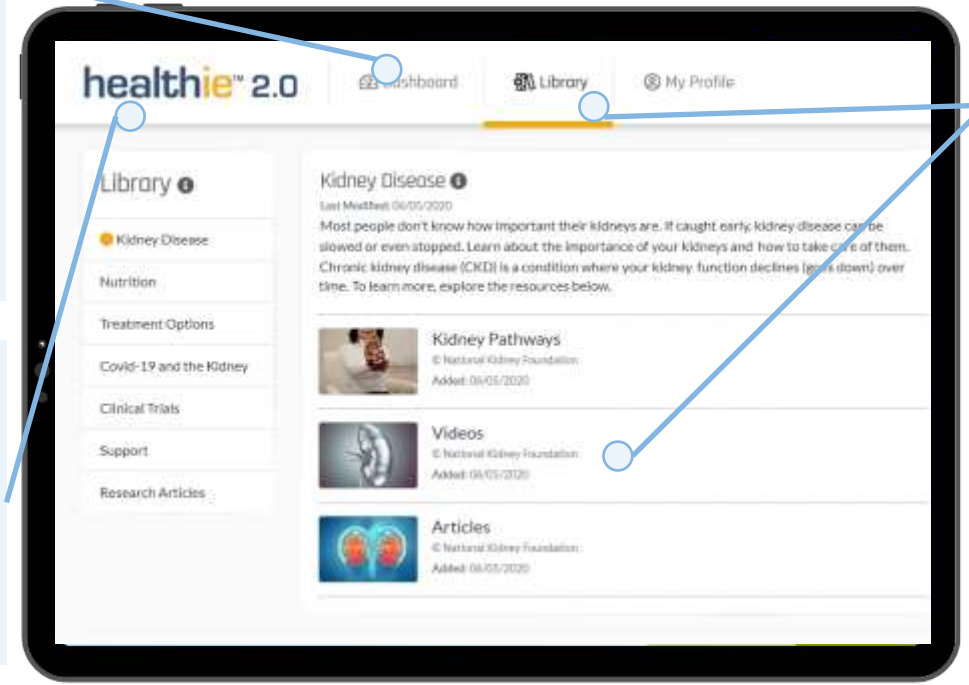
Case Study:
Hybrid Registry – 2 of 2

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

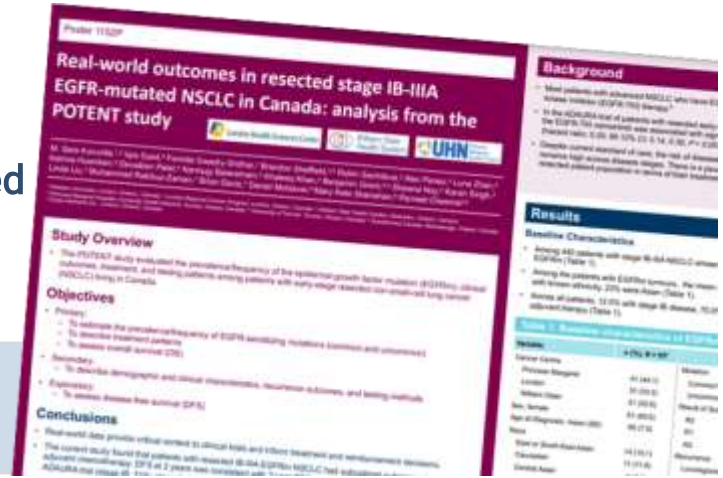
Case Study:

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.



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 BRAZIL | SLEEP 2023 JUNE 3–7 | INDIANAPOLIS, IN | WORLD SLEEP 2022 | SLEEP 2022 | PEDIATRIC

- ✓ 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.

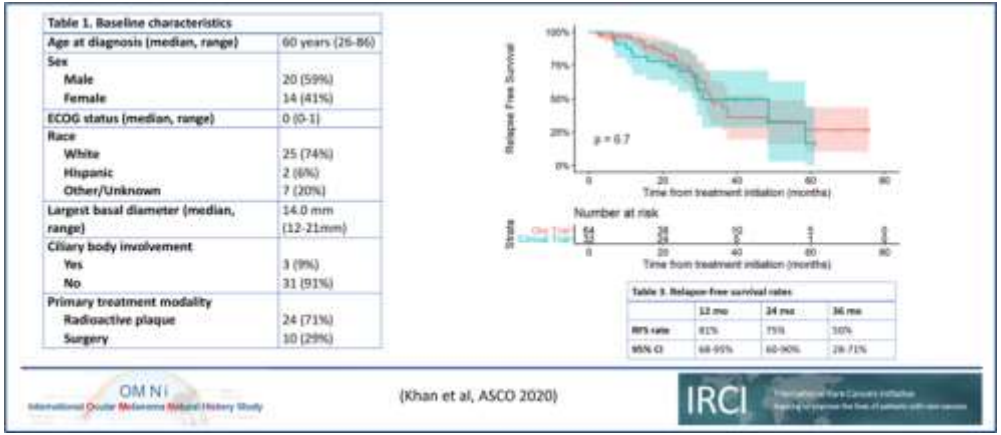

Table 1. Baseline characteristics	
Age at diagnosis (median, range)	60 years (26-86)
Sex	
Male	20 (59%)
Female	14 (41%)
ECOG status (median, range)	0 (0-1)
Race	
White	25 (74%)
Hispanic	2 (6%)
Other/Unknown	7 (20%)
Largest basal diameter (median, range)	14.0 mm (12-21mm)
Ciliary body involvement	
Yes	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

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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Melanoma

Global Melanoma Research Network

WHAT WAS THE ISSUE?

The original purpose for the **GMRN registry** when it was developed 10 years ago was to understand how patients are doing after they've received treatments for melanoma. It would address the following:

- What are the benefits?
- What are the outcomes?
- Are there differences based on practice, region, and/or province?

WHY WAS IT NEEDED?

Patients are data generators: they're research partners. Those participating in the **GMRN registry** want to know what the impacts and/or results of the treatments they're undergoing were.

HOW WAS IT DEVELOPED?

The **GMRN registry** makes use of the healthie™ platform which provides a collaborative ecosystem made up of researchers, patients, and industry for drug development increases the chances for developing treatments that truly benefit patients. A platform that supports the voice of the patient while collecting rigorous, regulatory grade data is the solution that can propel research that truly benefits patients.

WHAT ARE THE RESULTS?

Treatments have evolved over the last 10 years, and the **GMRN registry** has provided both the research and medical communities opportunities to ask detailed questions to not only advance treatments but also to improve treatment outcomes for and impact on patients. As the registry expanded, it's been possible to extend the platform to support subtypes of skin cancers, e.g., Merkle cell, squamous cell, and basal cell carcinoma. Researchers can leverage one platform for exploring multiple other malignant diseases.

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GMRN registry

IMPACT OF THE REGISTRY

"Over the past 10 years, the Global Melanoma Research Network team has been able to track the impact on patients and the efficacy of treatment: Is the treatment having a positive impact? How does the RWD compare to the favorable results reported from the clinical trials?"

Dr. Scott Ernst, PI for Global Melanoma Research Network

4,900+ PATIENTS ENROLLED

Since its launch, the **GMRN registry** was enrolled over 4,900 patients and this number continues to increase

2012 LAUNCH

The **GMRN Registry** was launched in 2012 and the London Regional Cancer Program the first site to register patients. The evidence generated from the platform has been leveraged by over 6 pharma companies for prospective and retrospective(longitudinal), HEOR, quality of life and epidemiological studies

PUBLICATIONS

Data from the **GMRN Registry** has been used in more than 6 publications to increase the understanding of the disease and treatment efficacy. Additionally, over two dozen abstract have been published

15 SITES

With 12 sites throughout Canada, the **GMRN Registry** is the largest registry for the disease in the region

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Impact of systemic therapy sequencing on overall survival for patients with advanced BRAF-mutated melanoma

Authors: B Adi Kartolo, Jasna Deluce, Wilma M Hopman, Linda Liu, Tara D Baetz, Scott Ernst, John G Lenehan

Division of Medical Oncology, Cancer Care of Southeastern Ontario, Queen's University, Kingston, ON; Division of Medical Oncology, London Regional Cancer Program, London Health Sciences Centre and University of Western Ontario, London, ON; Department of Public Health Sciences, Queen's University, Kingston, ON; Pulse Infoframe, London, ON

Background:

- No clear guideline recommending optimal first-line (1L) therapy in BRAF-mutant melanoma
- Immune checkpoint inhibitor (ICI) vs. BRAF targeted therapy (TT) – does treatment sequencing matter?
- Here, we provide real-world evidence utilizing prospectively collected data from the Canadian Melanoma Research Network (CMRN) database

Methods:

CMRN (9 Cancer Centres in Canada)
Prospective data collection

Inclusion Criteria:
-Unresectable advanced/metastatic cutaneous melanoma
-Targetable BRAF subtypes
-At least 1 cycle of palliative-intent ICI or TT
-At least 1 year follow-up

Exclusion Criteria:
-MEK without BRAF inhibitor
-1L ipilimumab monotherapy

1L ICI	1L TT
PD-1±CTLA-4 inhibitors with or without subsequent BRAF±MEK inhibitors	BRAF±MEK inhibitors with or without subsequent PD-1±CTLA-4 inhibitors
(N=80)	(N=151)

Study Endpoint: Overall Survival (OS) via Kaplan Meier
Multivariable Cox Analysis: ECOG, number of metastasis, brain metastasis, sequencing group

TAKE HOME MESSAGE

Using ICI in first-line shows a trend to improved survival when compared to TT in real-world patients with advanced BRAF-mutant melanoma. 1L-IO patients have a lower chance of requiring second-line therapy due to progression.

MAIN FINDINGS

Figure 1. Overall Survival Based on Treatment Sequence Group

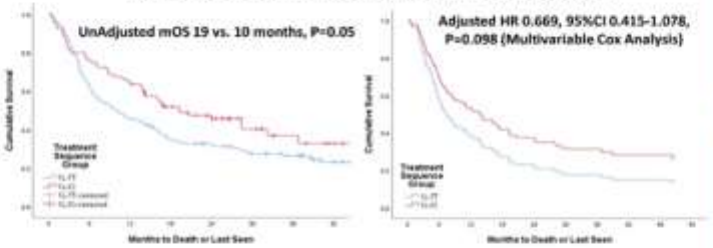

Figure 2. Treatment Sequencing Pattern Based on 1L Regimen

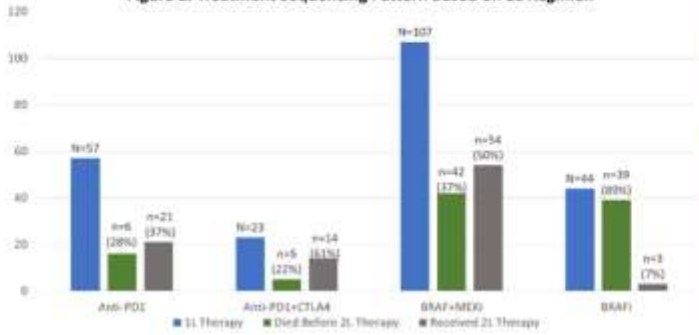

Table 1. Baseline Study Characteristics

	Total (N=231)	1L-ICI Group (N=80)	1L-TT Group (N=151)	P-Value
Age ≥65	118 (51)	44 (55)	74 (49)	0.409
Male Gender	149 (65)	55 (69)	94 (62)	0.386
ECOG ≥2	31 (13)	5 (11)	26 (32)	0.010
LDH >Median (280)	88 (38)	34 (52)	54 (50)	0.756
Number of Metastatic Sites ≥2	110 (48)	42 (52)	68 (45)	0.333
Baseline Brain Metastasis	65 (28)	17 (21)	48 (32)	0.094
Received Palliative RT	139 (60)	46 (56)	93 (62)	0.574
Received Palliative Surgery	15 (6)	6 (8)	9 (6)	0.780

Table 2. Characteristics of 2L Therapy

	1L-ICI	1L-TT	P-Value
Received 2L Therapy	35 (44)	57 (38)	0.399
Reason for 1L Therapy Discontinuation			
Progression	30 (38)	85 (57)	<0.001
Toxicity	17 (21)	16 (11)	
Treatment Completion/Ongoing	18 (22)	11 (7)	
Unknown	15 (19)	38 (25)	
2L Therapy			
Anti-PD1	-	42 (74)	N/A
Anti-PD1 + Anti-CTLA4	-	15 (26)	
BRAFi + MEKi	35 (100)	-	
Reason for 2L Permanent Discontinuation			
Progression	22 (62)	30 (53)	0.619
Toxicity	3 (9)	4 (7)	
Treatment Completion/Ongoing	7 (20)	19 (33)	
Unknown	3 (9)	4 (7)	

Table 3. Multivariable Cox Analysis for Overall Survival

	Overall Survival		
	HR	95% CI	P-Value
Number of Metastatic Sites ≥2	2.230	1.432-3.474	<0.001
Baseline Brain Metastasis	1.317	0.841-2.062	0.228
Baseline ECOG≥2	2.666	1.667-4.263	<0.001
Sequencing Group (1L TT as Reference)	0.669	0.415-1.078	0.098

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Contact

Joshua Henderson, Head of Rare Diseases
jhenderson@pulseinfoframe.com

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