

Beyond Human Factors: Identifying the Barriers to *Real-World Use*

Human factors validates that your device can be used safely and correctly.

RWUR identifies the barriers between validation and adoption.

D A T E

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R W U R P R A C T I C E L E A D



Alper Hulusi

Head of Market Insights, ClariMed

25 years in qualitative research, 13 focused on medical devices. Lead of ClariMed's Real-World Use Research practice. Field experience spans neuromodulation, diabetes care, cardiovascular, and rehabilitation programs from early exploration through post-market evaluation.

Human factors gets your device through validation. The barriers to real-world use sit just beyond that line.

A device that performs flawlessly in a usability study can still face barriers to adoption that no human factors protocol was designed to surface.

Those barriers form both before and during product development, but become visible only later, as launches that stall, prescribers who hesitate, and users who try the device and quietly stop. The cost is rarely traceable back to its origin.

*We are calling it **Real-World Use Research, or RWUR**. It extends our work into the territory of understanding unmet and ill-met needs, fit with lifestyle and context, so that products are grounded in the realities of human experience — as well as the territory of adoption, sustained use, and commercial outcomes.*

SESSION OVERVIEW

What we will cover in the next 60 minutes

01	Where adoption barriers form, and why they go unseen <i>The territory RWUR exists to investigate, alongside human factors</i>	10 min
02	The four RWUR moments in development <i>When each adoption barrier becomes visible, and what is at stake at each one</i>	15 min
03	RWUR in the field: three programs <i>Examples from neuromodulation, diabetes care, and stroke rehabilitation</i>	15 min
04	RWUR alongside human factors <i>How both disciplines work from one brief and produce stronger evidence</i>	10 min
05	The RWUR diagnostic <i>A take-home framework for assessing where your own program stands</i>	5 min
→	Complimentary RWUR Review <i>Working session for qualifying device teams</i>	5 min

Leading ClariMed's Real-World Use Research practice



Alper Hulusi

HEAD OF MARKET INSIGHTS, CLARIMED ·
RWUR PRACTICE LEAD

25 years of qualitative research experience, with 13 years focused on medical devices across therapeutic categories and complex user populations. Field work spans neuromodulation, diabetes care, cardiovascular, rehabilitation, and stroke recovery programs, working with people, caregivers, clinicians, and commercial decision-makers from early exploration through post-market evaluation. Member of the Market Research Society and the Association for Qualitative Research. Key driver of the four RWUR moments framework introduced in today's session.

SECTION 01 · THE CASE FOR RWUR

Where adoption barriers form, *and why they go unseen*

01

Four common gaps that RWUR is designed to close

Internal expertise carries its own lens	Internal expertise sometimes reflects a particular lens, perspective, and subtle bias drawn from a familiar pool of users and experts. RWUR adds truer, more detailed, more grounded evidence about this user, the buyer, the prescriber, in the conditions they actually face.
Human factors validates use; RWUR investigates adoption	Human factors confirms the device can be used correctly. RWUR investigates whether users will need it, choose to use it, like it, or benefit from it (quality of life, outcomes, daily fit). All are essential, and they answer different questions.
Buyer, user, and prescriber are three audiences	In most device categories these are three different people with three different decision drivers. RWUR places the spotlight on all relevant parties, early on, so product designs go in eyes wide open.
The right time for RWUR is earlier than it feels	Adoption barriers form from the get-go — pre-development (inadequate scoping of unmet needs or appetite for something different) and during development. Each moment is an opportunity to tease out barriers and stoppers, and to address them.

Why adoption barriers stay invisible for so long

THE DELAY PROBLEM

The impact of the barrier appears far from where it formed

An adoption barrier that surfaces its head during early-stage research doesn't always resonate with sales at that point in time — it just isn't felt then. The impact surfaces eighteen months later as a flat sales curve, or two years later in a board review.

The cost of skipping RWUR is invisible at the moment when investing in it would have been cheapest.

THE CONFIDENCE PROBLEM

The concept is well understood; adoption drivers and user needs sometimes are not

Internal clinical expertise, mechanical engineers, wider teams, KOL conversations, and usability studies create well-founded confidence at the concept level. That confidence is sometimes based on incomplete knowledge and insights, and misses the full picture of who decides, who pays, who wants, and why.

RWUR is designed to reveal the appetite and inclination to use and procure, and the drivers behind these.

THE TIMING PROBLEM

RWUR often feels premature, or an unnecessary expense

Early in development, the design feels too unstable to commission research. Later, the launch plan feels too committed to change. The window that genuinely exists is rarely recognized as the right moment to act.

The most useful RWUR often feels premature, or an unnecessary expense, because funds are tight. But it's often never too early!

SECTION 02 · THE RWUR FRAMEWORK

The four moments *of RWUR in development*

02

Every device program has four moments where adoption barriers can be identified and addressed

MOMENT 01 · EARLY-STAGE EXPLORATION

01

Is the problem we are solving the problem the audience actually has?

Product framings are often gauged against KOL conversations, clinical literature, and friendly users who happen to be available — not against how people with conditions, clinicians and beyond actually experience their reality, or what they want and need. Let's get out there, see, explore, and understand the true experiences and needs of the target audience.

MOMENT 02 · DESIGN STAGE

02

Does the proposed solution align with users' real-world experience?

Noisy children, a frantic lifestyle, the emotional and physical burden associated with living with a condition — all shape how someone feels about and uses a device. RWUR pairs human factors evidence with adoption evidence about how users will integrate the device into their actual routines.

MOMENT 03 · PRE-LAUNCH

03

Will the buyer, user, and prescriber each have reason to choose us?

In most device categories there are three different people with three different decision drivers. A launch plan that treats them as one audience, or fails to engage one or more of the three, soon discovers it has failed to understand core adoption drivers.

MOMENT 04 · POST-LAUNCH

04

Is actual usage matching projected usage, and what explains the gap?

Sustained use equals commercial success. RWUR closes the loop by learning from non-adopters, adapters, and those who move to competitor products. The key is to understand the how, the why, and what can be done to ensure uptake and usage are sustained.

Human factors and RWUR answer different questions about the same device, and produce stronger evidence together

HUMAN FACTORS ANSWERS

Can the user use the device, perform the task safely, reliably, and as intended, under realistic conditions? Human factors engineering is built to address the match between device design and the cognitive and physical capabilities of the intended user population. It is the foundation that any adoption work depends on.

RWUR ANSWERS

Will the user want, need, like, and choose the device? Will the prescriber recommend it, will the buyer keep paying for it, and will users stay on it? RWUR investigates the adoption barriers that human factors validation is not designed to surface, in the moments where they can still be addressed.

TOGETHER THEY PRODUCE

A complete view of what users can do, will do, and will keep doing with your device. Human factors and RWUR work from the same brief and reinforce each other, giving product, clinical, and commercial teams evidence they can act on at every stage.

SECTION 03 · RWUR IN THE FIELD

Three programs, *three sets of barriers*

03

The barriers to real-world use look very different across devices, users, and buyers

RWUR · NEUROMODULATION

Implantable neurostimulation for chronic condition management

Three audiences who must each say yes: the implanting specialist who recommends, the referring clinician who screens candidates, and the person with the chronic condition, who decides whether they want to use the system, use it to its full potential, and is happy to continue using it.

RWUR insight: Programs that win the implanter and lose the referring clinician spend launch budgets on the wrong audience. Contented users drive long-term economic success.

RWUR · DIABETES CARE

Continuous glucose monitoring and insulin delivery for people with Type 1 diabetes

So many complex variables come into play where CGM and insulin pump use are concerned — the device, the data, stress, tiredness, food, exercise, sleep, the list goes on. Don't forget the consultants, the caregivers, the schools — all play a key role in a person's diabetes care, alongside prescribing consultants and their increasingly tight reimbursement windows.

RWUR insight: The needs, demands, and challenges faced by a teenager managing exam stress or a game of football are not the same as those of a corporate executive crossing time zones to present to the board. Adoption relies on a product meeting complex, versatile needs and conditions.

RWUR · STROKE REHAB

Recovery and rehabilitation device for people post-stroke living with communication impairment

People living with aphasia or motor impairment, caregivers managing daily routines, rehab clinicians prescribing across acute and community settings, health system buyers evaluating outcomes contracts.

RWUR insight: RWUR uses varying research methods to suit different populations — from people living with impaired cognition and speech, to empathetic caregivers — so that unique experiences, needs, and desires are teased out.

Seeing through the eyes of the people we research

So far, we have covered why RWUR matters and to what end. How we go about doing RWUR matters just as much.

“Seeing with the eyes of another, listening with the ears of another, feeling with the heart of another.”

ALFRED ADLER · FOUNDER OF THE SCHOOL OF INDIVIDUAL PSYCHOLOGY

This philosophy holds across every RWUR study, regardless of who the research is with:

01 Surgeons

Understanding their protocols, experiences, pressures, pain points and anxieties.

02 People with diabetes

Understanding how insulin pump and CGM use is shaped by daily routine — at work, at home, at the cinema, on a date. How that looks, feels, impacts.

03 Hospital procurement

Understanding the priorities, motivations, and pressures team members are under. Understanding what resonates, and why.

The tools and techniques that bring it to life

A plethora of methods that allow us to do what Adler suggests — and our approach differs from human factors in important ways but also shares some similarities.

01

Exploratory in-depth interviews

In situ (ideal), at a facility, online

Best for understanding an individual's unique experiences, views, needs, and motivations.

Dynamic, probing, sensitive, and responsive — and sometimes involve constructively challenging views in order to gain further insights. Gets to the bottom of what it's like using a device.

02

Focus groups

Group sessions, in person or online

Ideal when generating marketing collateral, exploring blue-sky concept ideas or encouraging groups to share challenges and identify solutions.

The ago-old concern about dominant voices overshadowing others is easily dealt with!

03

Observational methods

In the field, in the moment

Best for contextually rich, grounded insights, whether researching with people living with obesity, GPs, or anywhere context shapes behavior.

Sometimes participant observation, other times non-participant - the goal remains the same, which is to expose and unpick experiences/behaviors, and what fuels them.

How our approach differs: *dynamic, interpretive, probing, exploratory, open and responsive to the unexpected.*

SECTION 04 · RWUR ALONGSIDE HUMAN FACTORS

One brief,
*two complementary
lenses*

04

SECTION 04 THE INTEGRATED APPROACH

What both disciplines produce when they work from the same brief

- A grounded, 360-degree view of what needs to be developed, who it needs to be developed for, and why
- An in-depth understanding of each population's unique and shared views, covering all perspectives
- Insight that allows teams to design in a truly inclusive manner, helping them mitigate barriers from the start
- Risk management documentation built on comprehensive, inclusive real-world insights
- Hybrid insights that combine a safety and usability lens with a preference and adoption lens, a powerful combination

THE CLARIMED POSITION

RWUR extends and complements human factors work, and vice versa

*Together, RWUR and human factors give R&D, clinical, and commercial teams a complete view of **how (and why)** their device should be developed, **for whom**, and **how it will perform**. A joint lens, a joint vision, with real-world needs driving activities, aiming for real-world adoption.*

SECTION 05 · THE RWUR DIAGNOSTIC

**Where does your
*RWUR program stand?***

05

Apply the four RWUR moments to your own device program today

MOMENT 01 · EARLY-STAGE

Is the problem we are solving the problem our users actually have?

- Spoken directly with people, clinicians, or caregivers in their own words?
- Unmet need framing examined against day-to-day lived experience?
- Characterized the workarounds people rely on, and what would make them switch?

MOMENT 02 · DESIGN

Does our solution map to how this user actually works in real conditions?

- Design observed in actual settings, with realistic variability in conditions?
- Human factors evidence paired with adoption evidence on workflow integration?
- Adaptation behaviors from analogous devices informing your design choices?

MOMENT 03 · PRE-LAUNCH

Will buyers, users, and prescribers each have reason to choose us?

- Separately characterized the buyer, user, and prescriber's decision drivers?
- Purchase process, budget cycle, and gatekeepers known via primary research?
- Positioning, pricing, and messaging explored with actual decision-makers?

MOMENT 04 · POST-LAUNCH

Is actual usage matching projected usage, and what explains the gap?

- Measuring sustained use against projected adoption curves, not just shipments?
- Structured way to learn from non-adopters and users who started and stopped?
- Field workarounds visible to product, clinical, and commercial teams?

COMPLIMENTARY FOR WEBINAR
ATTENDEES

The RWUR Review

A structured 60-minute working session with Alper Hulusi, lead of ClariMed's RWUR practice, for medical device teams who want an expert perspective on where adoption barriers may be forming — mapped to the four RWUR moments.

- 60-minute RWUR Review with Alper Hulusi
- Complimentary for qualifying teams with active device programs
- Written RWUR summary delivered after the session
- Priority scheduling for requests within two weeks of this webinar
- We confirm fit before scheduling

TO REQUEST YOUR RWUR REVIEW

Tell us about your device program

RWUR Reviews are open to medical device teams at any stage of the product development lifecycle — from early-stage exploration through pre-launch positioning and post-market evaluation. We confirm fit before scheduling.

- Product, clinical, human factors, and commercial teams welcome
- Active device programs at any development stage — we confirm fit before scheduling
- Available via clarimed.com following this session

REQUEST AN RWUR
REVIEW →

THANK YOU · THE RWUR QUESTION

The question behind every device program

*What stands between your validated device and the people who were supposed to use it? That is the **RWUR question**, with specific methods, four critical moments in development when it can be answered, and commercial consequences that depend entirely on when and how it is asked.*

NEXT STEP

Request an RWUR Review