



Introduction

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Breaking the barriers: functional neurological disorder in the era of digital healthcare

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Functional neurological disorder (FND) is among the most common conditions in neurological practice and among the most poorly served by it. Two things have now changed at once. The science has moved on: FND is increasingly investigated using network, predictive-processing and agency-based models rather than treated as a diagnosis of exclusion, although the specificity, causal status and clinical use of these models remain under study. Digital care has moved beyond teleconsultation and stand-alone applications towards adaptive systems combining remote monitoring, artificial intelligence and machine learning, robotics, neurotechnology and extended reality in the home. Their coincidence is the reason for this collection. It is also the reason for its central argument—once these elements interact, the unit of evaluation is no longer a device or an algorithm but a sociotechnical care system, and the discipline required to build one is systems engineering, anchored at both ends in lived experience.

This article is part of the discussion meeting issue 'Digital healthcare for the management of functional neurological disorders'.

1. A field at an inflection point

Functional neurological disorder (FND) is a common, disabling and often misunderstood neurological condition characterized by involuntary symptoms affecting movement, sensation and cognition and by episodes resembling seizures [1]. Estimates of its frequency in neurological practice vary with setting and case definition: reported minimum prevalence is of the order of 80–140 per 100 000 [2], while individual studies have described FND as accounting for approximately 9% of neurology admissions and 16% of neurology clinic referrals [3]. Despite this, people with FND commonly experience prolonged diagnostic pathways, repeated consultations, multiple investigations and delayed access to specialist rehabilitation or psychological support.

This reflects a longer predicament. For more than a century, FND has occupied an uncomfortable borderland between neurology and psychiatry, between the 'organic' and the 'psychogenic', and between what could be visualized on a scan and what patients genuinely experienced [4]. Charcot's intuition of a 'functional lesion' captured a truth that structural pathology could not explain, yet the field long lacked the tools to render that intuition mechanistically precise. That gap bred not only diagnostic uncertainty but also enduring stigma, a legacy that persists even as understanding advances [5].

The tone of this theme issue marks a decisive break from that history. FND is characterized here as a condition of genuinely experienced, involuntary and distressing symptoms, distinguishable from other neurological diagnoses in presentation, aetiology and mechanism—a framing that repudiates older dualist assumptions and affirms the reality of patients' experience [5,6]. Contemporary aetiological models locate symptom formation in prior belief, expectation and disordered sensorimotor processing rather than in feigning, and the disorder is increasingly conceptualized as one of network-level dysfunction involving altered salience processing, impaired coupling of motor intention to execution and disrupted self-agency [1,6].

This conceptual maturation has been matched by institutional recognition. The National Health Service (NHS) England's specialized neurology service specification now includes FND within its minimum service expectations, requiring specialized centres to provide access to appropriate FND pathways—an operational commitment that treats FND as a mainstream neurological responsibility rather than a diagnosis of exclusion [7]. In parallel, the National Institute for Health and Care Excellence (NICE) guideline NG252, published in October 2025, covers rehabilitation for chronic neurological disorders and explicitly includes FND alongside acquired brain and spinal cord injury and progressive neurological disease, calling for person-centred, lifelong and integrated rehabilitation coordinated across hospital, community and social care [8]. Read together, these developments place FND within the same commissioning, rehabilitation and quality frameworks as its structural counterparts.

The second change is technological, and its consequence is conceptual. Once monitoring, adaptation, actuation and immersion interact in a person's home, the object of evaluation becomes a sociotechnical care system comprising the person with FND, family or carers, clinicians, workflow, data, software, hardware, environment, funding and governance. A system can contain components that each perform well and still fail because its interfaces, assumptions or incentives are wrong [9]. This theme issue therefore asks a deliberately demanding question: what has to be true for digital healthcare to reach, and durably help, people with FND?

The issue arises from the Royal Society scientific meeting *Digital healthcare for the management of functional neurological disorders*, held on 25–26 November 2024, which convened neurologists, psychiatrists, physicists, engineers, health economists and neuroscientists to define a shared research and clinical agenda.

2. Functional neurological disorder as exemplar, not exception

Predictive-processing accounts frame FND as a disorder of active inference in which overly precise priors override incoming sensory input to generate aberrant sensations and movements, explaining the symptom expectation, illness beliefs and loss of self-agency at its core [6]. Critically, this logic is not unique to FND. It places the disorder within a family of conditions including chronic and nociplastic pain, fibromyalgia and fatigue syndromes with overlapping neural signatures described across modalities, although the cited review is explicit that their specificity remains uncertain, and they may reflect non-specific transdiagnostic processes [10].

This overlap has three consequences that the field has been slow to draw out:

- **mechanistically**: work on one condition generates evidence for the others. Wylie's [11] model of fatigue in this issue is deliberately domain-general, importing rigour from cognitive neuroscience into the most commonly reported yet least understood of FND symptoms;
- **therapeutically**: shared or overlapping mechanisms may motivate carefully designed transdiagnostic studies, but they do not by themselves establish that treatment effects transfer between conditions: dose, mechanism, phenotype, safety and clinical context may all differ; and
- **economically and politically**: these conditions share not only a neural signature but a fiscal signature—high disability, low mortality, dominant indirect costs and consequent near-invisibility to conventional health-technology appraisal [3].

The constituency for investment in FND-directed technology is therefore far larger than FND alone. It encompasses a substantial share of the chronic, fluctuating, high-disability illness for which many health systems provide fragmented or insufficiently resourced care.

3. The unmet need and the ambivalence of the digital moment

Stone provides the integrative clinical frame [12]. FND is among the most common conditions encountered in neurological practice, yet it has been persistently neglected, the combination of high prevalence, substantial disability and historical marginalization has created unmet needs across diagnosis, treatment and service delivery. He identifies six domains in which digital healthcare could effect change—mining large biobank and clinic datasets to reveal epidemiology, comorbidity, mechanism and economic burden, augmenting time-consuming assessment with artificial intelligence (AI), improving diagnostic precision through automated tremor analysis, quantification of functional motor signs and speech recognition, expanding self-management and access to therapy through online tools and telehealth, strengthening outcome measurement with wearables and enabling new therapies including biofeedback and virtual or augmented reality.

He tempers this optimism with warnings of depersonalization, privacy breach, therapeutic substitution, digital dependence and digital exclusion, and notes that therapist effects—variability driven by the clinician rather than the intervention—remain

Table 1. The translational loop, and where each contribution sits within it.

layer	question it answers	contributions in this issue
requirements	what problem, for whom, at what value?	Stone [12], Bandyopadhyay <i>et al.</i> [13]
specification	what state should change, and why?	Lozzi <i>et al.</i> [15], Wylie [11], Deeley [16]
observation	can the state be measured in real life?	Pick & Hotopf [17], Rude & Kutz [18]
actuation	can we act on it therapeutically?	Di Bilio <i>et al.</i> [19], Morgan <i>et al.</i> [20], McGlone [21], Deeley [16]
integration	do components behave as one system, in the home?	Farkhatdinov <i>et al.</i> [22]
verification, value, access	is it safe, effective, affordable, reachable?	React2Home, early HTA, regulatory pathways

difficult to replicate digitally [12]. This matters because FND care depends on explanation, trust, attention, expectation and therapeutic alliance.

A technically sophisticated system can therefore be clinically counterproductive if it increases symptom surveillance, implies disbelief, overwhelms the user, transfers responsibility without support or removes access to human care. The design requirement is not simply to digitize existing care but to use technology to humanize it, extend it and make it more consistent.

4. The burden we have systematically undercounted

Bandyopadhyay *et al.* [13] provide the economic counterpart to Stone's clinical frame, and their argument is uncomfortable—FND's total economic burden remains uncertain and incompletely characterized, and that uncertainty is itself a barrier to care. The epidemiology is too imprecise to fund—an incidence of 10–22 per 100 000 and a minimum prevalence of 80–140 per 100 000, against a possible range of 50–1600, reflecting methodological rather than biological variance with even the best estimates believed to understate the true figure once stigma and under-ascertainment are allowed for [2,13].

The costs, meanwhile, fall largely outside the health service. In one UK tertiary-clinic cohort of 118 patients, mean direct NHS costs over the preceding six months were approximately £3328 per participant and estimated informal-care costs over the same period approximately £9255, while estimated loss of employment income averaged approximately £6594 annually [14]. These figures derive from different costing methods and reporting periods, rest on replacement-cost assumptions for informal care and a selected tertiary cohort, and should not be read as nationally representative, but they indicate that costs falling outside the health service are unlikely to be small, and most studies count only direct medical costs [3,13]. The consequence is a closed circle—understated prevalence understates burden, burden measured only through NHS spend omits the larger share of the loss, and interventions are then appraised against a metric—the quality-adjusted life year—which, depending on the utility instrument and analytic perspective, may incompletely capture changes in participation, independence, carer burden and social functioning. These limitations justify examining whether complementary approaches—including severity modifiers, broader societal perspectives and, where appropriate, generalized risk-adjusted cost-effectiveness—would alter conclusions in FND, each carries its own assumptions and estimation demands and none is an established FND-specific appraisal standard [13]. We therefore place economics at the front of the translational loop rather than at its end.

5. A human-centred translational loop

Drawing the contributions together, we argue for a translational loop (table 1) in which lived experience defines the problem and constrains the design, mechanistic models specify what should change, observation technologies make the relevant states measurable, interventions act on those states, integration turns components into care and verification, validation, health-economic evaluation and access determine whether the resulting system is safe, useful, valuable and deployable.

Micera & Agnesi's [9] argument that neuroengineering should be treated as a systems-engineering discipline supplies the broader frame—translational failure more often reflects inadequate system integration than the weakness of any single component, and the remedy is to import the proven machinery of requirements engineering, architecture definition, subsystem design, integration and verification and validation (V&V) from the outset. We extend that thesis for FND. Systems engineering needs a legitimate source of requirements, and in a heterogeneous, relational and historically marginalized condition, those requirements must begin with lived experience. Co-design and systems engineering are complementary—experience-based co-design (EBCD) helps determine what should be built and which outcomes matter, systems engineering makes those decisions explicit, testable and traceable.

A protocol from one of the Guest Editors' groups provides a concrete worked example. React2Home uses EBCD to elicit the experiences and priorities of people with FND, carers and professionals, quality function deployment (QFD) to translate those

priorities into engineering specifications, Agile development to refine an AI/machine learning (ML)-enabled extended reality (XR) and haptic platform and staged V&V from engineering tests to clinical and at-home evaluation [23]. Its importance here is methodological rather than evidential—it is a protocol for constructing a traceable development and evaluation pathway, not proof that the intervention is clinically effective.

6. From lived experience to traceable requirements

For FND, co-design is not a consultation exercise performed after a technical concept has been selected. It is the front end of requirements engineering. Symptoms fluctuate with context, attention, expectation, fatigue and interpersonal interaction, a stimulus that supports agency in one person may provoke discomfort, loss of control or symptom amplification in another. Service constraints matter equally—a platform requiring specialist set-up, high-bandwidth connectivity, continuous supervision or expensive consumables may be unusable in precisely those settings where access is most limited.

React2Home operationalizes this position [23]. Narrative interviews, a trigger film and joint workshops identify emotional touchpoints and patient-, carer- and service-centred priorities for XR rehabilitation of functional limb weakness, these are translated into user stories and then into ranked engineering characteristics through QFD, while four-week sprints permit repeated testing and revision. Predesign work reported in the protocol found excellent usability for XR position-feedback tasks with System Usability Scale scores above 85 but substantial inter-individual variability for relaxation and force-feedback tasks. The lesson is not that one component ‘worked’ and another did not—heterogeneity, comfort, accessibility and personalization are system requirements that need acceptance criteria and evidence.

The rigorous output of co-design should be a bidirectional traceability spine—lived-experience evidence → clinical and user requirements → QFD-ranked design inputs → measurable acceptance criteria → verification protocols and results → validation outcomes → implementation and economic evidence. Every test should map to a requirement, and every requirement should have an evidence route. When a requirement changes, its associated risks, architecture, tests, clinical assumptions and economic consequences should be reviewed.

Two qualifications matter. EBCD validates the relevance and acceptability of proposed requirements, it does not by itself validate clinical benefit, regulatory conformity or cost effectiveness. QFD makes trade-offs visible but does not remove judgement—weighting methods, conflicts between stakeholder groups, minority and accessibility needs and decisions *not* to implement a request should all be documented. Standards for QFD and human-centred design can structure this work [24,25], but meaningful participation and accountable decision-making remain substantive obligations rather than procedural ones.

7. Requirements: equity and the value case

Equity must be specified rather than assumed. At-home delivery may reduce travel and specialist-access barriers, but it can also shift equipment, connectivity, space, confidence and troubleshooting burdens onto patients and families. Given that informal care already accounts for the single largest cost component in FND, an intervention that appears cost-saving from an NHS perspective may simply transfer cost to carers [3]. Requirements should therefore include accessibility across motor, sensory, cognitive and language differences, low-bandwidth and non-digital alternatives, escalation to human support, carer implications, data minimization and monitoring for differential dropout, error and benefit. ‘Personalization’ must not become a technical label for transferring responsibility to the user.

Early health technology assessment (HTA) belongs at this stage because value is partly designed. International consensus defines early HTA as an HTA conducted to inform decisions about subsequent development, research and/or investment by explicitly evaluating the potential value of a conceptual or actual health technology [26]. In practice, this means defining a target product profile, comparator, place in the pathway, threshold clinical benefit, plausible price, service-resource consequences and evidence needs while the design can still change [27,28]. Sensitivity and threshold analyses reveal which parameters carry the greatest decision value and whether further engineering or clinical research is justified.

Early HTA should not be overstated—it is performed with limited and evolving evidence, cannot substitute for clinical trials and is not a reimbursement verdict [26,27]. Its purpose is to expose uncertainty, test the coherence of the value proposition and guide design and go/no-go decisions. For FND, where benefits may include restored participation, reduced crisis use and reduced carer burden, the analytic perspective and outcome framework are themselves requirements to be co-designed since the choice between a payer and a societal perspective can invert the conclusion.

8. Specification: mechanistic and computational foundations

A system cannot be meaningfully verified or validated unless its intended mechanism and use are sufficiently specified. FND has historically resisted specification because its lesion is functional rather than structural. Three contributions deepen that specification in complementary ways.

Lozzi *et al.* [15] trace neuroimaging from Charcot’s intuition to the contemporary view of FND as a disorder of distributed networks. Task-based functional magnetic resonance imaging reveals atypical activation across the supplementary motor area, dorsolateral prefrontal cortex and temporo-parietal junction—regions governing motor control and the sense of self-agency—with amygdala and periaqueductal gray changes implicating emotional dysregulation, while ML applied to resting-state connectivity,

together with emerging genetic and epigenetic signals, offers a possible route towards imaging biomarkers that might in future support stratification and treatment-response monitoring, though no such biomarker is yet clinically validated. Their call for multi-modal integration is also a specification problem: what latent state is the system intended to estimate, at what temporal and spatial scale and with what clinical meaning?

Wylie [11] offers a domain-general model of fatigue, proposing that fatigue is generated when anticipated reward no longer justifies the effort required. By expressing a subjective and often neglected symptom in objective, testable variables drawn from cognitive neuroscience, the model converts a vague complaint into an engineerable specification with candidate observables and intervention targets.

Deeley [16] provides the computational and neuroanatomical bridge to immersive intervention, adopting the cortical hierarchy as a shared scaffold for hierarchical predictive coding, top-down signal routing and attractor dynamics, and asking how virtual reality might modulate symptoms by simulating veridical bottom-up sensory input. In these accounts, attention and expectation alter the pre-conscious weighting and editing of experience, XR acts on the same hierarchy from the opposite direction, by supplying controlled sensory consequences. That offers a mechanism for treatment and simultaneously imposes testable questions about dose, context, transfer, adverse responses and the specificity of claimed effects.

Mechanistic plausibility is not clinical validation. A biomarker may be associated with FND without being reliable for an individual, a model may explain a symptom without identifying the correct intervention and an AI system may predict an outcome using shortcuts unrelated to the intended mechanism. Specifications should therefore distinguish mechanistic hypotheses, analytical performance claims, clinical claims and adaptive-control objectives, with evidence appropriate to each.

9. Observation: making functional symptoms measurable

A system can support clinical decisions or closed-loop treatment only to the extent that the relevant state is observable, and FND's fluctuating, context-dependent symptoms are poorly characterized by clinic snapshots. Pick & Hotopf [17] argue that digital remote monitoring technologies could capture subjective and objective symptoms, mechanistic variables and outcome domains with a temporal resolution, ecological validity and flexibility that clinic-based assessment cannot achieve characterizing short- and long-term fluctuation, strengthening mechanistic models, improving outcome prediction and supporting personalized management in a chronically underserved population. In systems terms, they are the instrumentation layer that makes both V&V and closed-loop control possible.

The qualification 'deployed well' is essential. Measurement can burden users, amplify bodily vigilance, produce false precision or generate clinically unactionable alerts. Observation technologies need layered evidence: metrological and analytical verification of sensors and algorithms, validation against clinically meaningful reference measures, assessment of missingness, wear-time and behavioural reactivity, subgroup and context-specific performance, and demonstration that the resulting information changes care beneficially. Accuracy in a laboratory does not establish utility in a home.

Rude & Kutz [18] address the complementary challenge of inferring a high-dimensional state from sparse measurement. Their shallow recurrent decoder couples temporal sequence modelling with a shallow decoder to reconstruct whole-brain and behavioural dynamics from a small number of sensor time series. Paired with wearables or sensorimotor robots such reduced-order decoders could render continuous, ecologically valid monitoring computationally tractable at scale. Yet, reconstruction quality, uncertainty, distribution shift and clinical interpretability must be verified for the intended population and use: an elegant latent representation is not automatically a safe clinical state estimate.

10. Actuation: feedback, neuromodulation and therapeutic learning

With the target specified and observable, the issue turns to intervention—the actuation layer. Di Basilio *et al.* [19] examine neuro-feedback, through which individuals learn to modulate neural activity in real time, and argue that it is theoretically well motivated for the salience, motor-intention and self-agency circuits implicated in FND. Because direct evidence remains limited, they emphasize standardization of neural targets, feedback modality, training dose, control conditions, learning metrics and transfer. These are precisely the design inputs and acceptance criteria required to turn a promising paradigm into a verifiable intervention.

Morgan *et al.* [20] report a sham-controlled study of limbic-targeted transcranial electrical stimulation delivered at home, showing that low-intensity stimulation synchronized to sleep can increase N3 and rapid-eye-movement sleep duration in healthy adults, with the device well tolerated and blinding maintained. The work does not establish efficacy in FND but it illustrates the V&V features that matter—a defined physiological target, controlled stimulation, sham comparison, blinding assessment and home deployment and, given the prominence of disrupted sleep in FND and related disorders, exemplifies translation of a mechanistic insight into a scalable home-based intervention.

McGlone [21] expands the actuator space by presenting C-low-threshold mechanoreceptors—unmyelinated afferents projecting to dorsal posterior insular cortex that encode gentle, affective touch—reframed as 'vitamin-T' for neurological health and a plausible therapeutic lever in FND. Together with Deeley's XR analysis and the robotics contributions, these accounts displace the assumption that FND treatment must remain confined to psychological therapy and physiotherapy, extending it into sensory neuroscience, neuromodulation and neuromechanics.

For each actuator, the therapeutic claim should be decomposed:

- **verification:** was the prescribed stimulus delivered within tolerance?
- **mechanistic validation:** did the expected proximal response occur?
- **clinical validation:** did clinically meaningful outcomes (function, participation or quality of life) improve versus an appropriate comparator? and
- **transfer validation:** did effects persist and generalize beyond the feedback environment?

Safety assessment must consider not only physical exposure but also cybersickness, fatigue, symptom exacerbation, altered agency, dependence, frustration and delayed access to human care.

11. Integration and deployment: from modular platforms to the home

Digital healthcare succeeds or fails at integration, and two robotics contributions embody its principles directly. Farkhatdinov *et al.* [22] describe the HRX-1, a single-degree-of-freedom, direct-drive, modular and reconfigurable robotic device for investigating human sensorimotor control, deliberately positioned as a hub for multi-modal integration—combined with electromyography, functional electrical stimulation and electroencephalography, it allows muscle responses to external forces and the neural coordination of those responses to be studied together, across fundamental motor-control studies and clinical research in children with dystonia, stroke rehabilitation and FND therapy. For a disorder understood in terms of impaired motor intention–execution coupling and disrupted self-agency, the capacity to close the loop between neural command and mechanical consequence is of particular value, providing the transparent, high-fidelity force control required to probe the reflex gains and voluntary–involuntary interactions that distinguish functional from structural motor signs, potentially yielding the objective, quantifiable markers that Stone identifies as a priority [12]. Its user-centred, open-source and portable design also lowers the barrier to reproducible neuromechanics research. Modularity, documented interfaces and reusable test harnesses are not incidental engineering conveniences, they are the properties that allow subsystems to be changed, reused and revalidated without invalidating the whole system.

The React2Home protocol sets out an FND-specific architecture in which XR content, haptic robotics, behavioural sensing, wearable neuroimaging and AI/ML adaptation are intended to operate as one clinical system, its evaluation is prospective and no clinical results are yet available [23]. Component verification is necessary but insufficient. System-level verification should test interface contracts, timing, synchronization, calibration, data provenance, cybersecurity, authentication, sensor dropout, network interruption, actuator limits and transition to a safe state. Hardware-in-the-loop simulation, fault injection and representative use scenarios can expose design flaws and unresolved requirements before patient exposure.

12. Verification and validation as a lifecycle evidence architecture

Verification asks whether specified requirements have been met, validation asks whether the resulting system is suitable for its intended use and users. In complex digital FND care this distinction is necessary but not sufficient. V&V should be organized as a lifecycle evidence architecture in which each question is answered at the level where it arises.

(a) Requirements validation

Before design freeze, intended use, target population, care setting, workflow, foreseeable misuse, accessibility needs and clinically meaningful outcomes should be tested with people with FND, carers and professionals. EBCD is especially valuable because it reveals requirements invisible in a technical specification—emotional safety, control, explanation, trust and routes back to human support. The output is a justified and prioritized requirement set.

(b) Subsystem verification

Sensors, displays, haptic devices, algorithms and software modules should be tested against quantitative specifications for accuracy, latency, sampling, force or motion limits, rendering, calibration, reliability and failure behaviour, with risk controls verified rather than merely documented.

(c) Integration and system verification

The assembled system should be challenged under normal, boundary and fault conditions, covering data integrity across interfaces, clock drift, conflicting commands, model or sensor unavailability, cloud outage, loss of tracking, cybersecurity events, incorrect set-up and recovery. Acceptance criteria should include safe degradation and human override.

(d) Design and usability validation

Representative users should evaluate a production-equivalent system in actual or realistically simulated clinical and home environments, including motor, sensory, cognitive and language diversity, investigating both successful use and non-use. High average usability cannot compensate for a critical failure in a vulnerable subgroup.

(e) Clinical validation

Prespecified studies should test the claimed purpose with appropriate comparators and follow-up, separating immediate task performance, mechanistic change, learning, transfer to daily function and durability, with safety and subgroup heterogeneity analysed alongside benefit.

(f) Implementation and economic validation

Deployment evidence should address reach, adoption, fidelity, clinician and carer time, training, maintenance, digital exclusion, budget impact and opportunity cost. Given that indirect costs dominate in FND, trials should prespecify employment status, informal care hours and crisis service use as economic endpoints rather than relegating them to secondary analysis [3,13].

AI/ML adds lifecycle obligations because performance can change with data, context, users and software updates. International Medical Device Regulators Forum [29] good ML practice principles emphasize multi-disciplinary expertise, representative datasets, independent test sets, human–AI team performance, clear user information and monitoring of deployed models. For adaptive systems, developers should prespecify what may change, the limits of adaptation, data-quality and uncertainty checks, subgroup performance, validation and rollback procedures and accountability for updates, the Food and Drug Administration's (FDA's) guidance on predetermined change control plans provides one regulatory model [30] and the US Quality Management System Regulation, in force since 2 February 2026, incorporates ISO 13485:2016 by reference [31].

For FND, human oversight has particular significance. A model that adapts challenge, feedback or reinforcement should not infer distress, intentionality or readiness solely from opaque behavioural signals. Users and clinicians need understandable operating boundaries, the ability to pause or override automation, and a clear route for reviewing unexpected behaviour, with traceability sufficient to support investigation without creating excessive surveillance.

13. Translation, regulation, value and access

Academic and clinical medical-technology research should be organized around a credible product and service pathway rather than ending with proof of concept. Schalk *et al.* [32] argue that successful neurotechnology translation requires simultaneous attention to technical, clinical and commercial requirements, genuine user needs and selection of the right clinical problem. Chiappalone *et al.* [33] connect scientific progress with entrepreneurship and viable, scalable products rather than isolated demonstrations, and reviews of neural prostheses show that product architecture, manufacturing, intellectual property, regulation, reimbursement and risk management must influence early design [34,35]. These lessons apply to digital FND care even when the technology is non-invasive.

The UK–USA comparison should remain balanced. The UK's potential comparative advantage is institutional adjacency—the Medicines and Healthcare Products Regulatory Agency (MHRA) regulates products, NICE evaluates clinical and cost effectiveness for NHS use in England, devolved nations have distinct HTA and adoption arrangements and the NHS offers an integrated setting for evidence generation and implementation. The Innovative Devices Access Pathway pilot brought the MHRA, NICE, Health Technology Wales, the Scottish Health Technologies Group and other partners together around selected technologies, although it is now closed to new applications [36] while NICE's consolidated HealthTech programme and early-use approaches provide mechanisms for guidance and evidence generation [37]. This architecture creates an opportunity to align an explicit chain—unmet NHS need → target product profile → regulatory evidence → comparative clinical value → cost effectiveness → implementation and procurement—but it does not guarantee rapid adoption, adequate funding or consistent access.

The USA combines a powerful regulator, substantial investment and a much larger commercial market but authorization and payment remain institutionally distinct—FDA marketing authorization does not by itself secure Medicare coverage, coding or payment, and private payers may impose further requirements. The Total Product Life Cycle Advisory Program provides earlier and more frequent development interaction, and FDA–Centers for Medicare & Medicaid Services (CMS) Parallel Review can align review of pivotal evidence for eligible products [38,39]. In April 2026, CMS and FDA [40] announced the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway for certain Class II and III Breakthrough Devices, with implementation awaiting the final procedural notice and the Transitional Coverage for Emerging Technologies pathway paused for new candidates rather than retrospectively erased. Comparative research cautions against simple rankings: authorization evidence, review times, post-market obligations and reimbursement decisions vary substantially across countries and devices [41]. For FND, research should be designed from the start to answer both regulator and payer questions, while retaining the outcomes that matter to patients.

14. A unifying vision: humanizing care by design

Taken together, these articles indicate that FND is increasingly approached as a disorder of brain network function that is becoming accessible to objective measurement, computational modelling and robotic assessment, and for which targeted interventions are being developed and tested. Placed side by side, they form more than a catalogue of digital opportunities: they populate a development system. Stone [12] and Bandyopadhyay *et al.* [13] define unmet need, constraints and value; Lozzi *et al.* [15], Wylie [11] and Deeley [16] specify mechanisms and targets; Pick & Hotopf [17] and Rude & Kutz [18] develop the observation layer; Di

Basilio *et al.* [19], Morgan *et al.* [20], McGlone [21] and Deeley [16] examine actuation; Farkhatdinov *et al.* [22] address modular integration and community deployment. What unites them is a refusal to work in isolation—imaging informs computation, computation enables monitoring, monitoring and robotics shape intervention and economic analysis determines which innovations reach patients.

The React2Home protocol illustrates how such a connection can be planned prospectively [23]. EBCD establishes patient- and service-centred requirements, QFD translates them into design inputs, iterative development and system-level verification expose flaws and unresolved interfaces, staged usability, construct, clinical and ecological validation test progressively stronger claims and early HTA asks whether a usable intervention could become a sustainable service. Systems-engineering thesis remains the enabling frame [9], and our contribution is to insist that the engineering system begins and ends with lived experience.

The decisive question is not whether digital healthcare can measure more, automate more or immerse more. It is whether the field can identify the right problem, co-design defensible requirements, verify that systems satisfy them, validate the benefits that matter, manage change across the lifecycle, count the full social and economic burden honestly and create a credible route to equitable access. A condition in which informal care and lost employment together dwarf direct healthcare spending cannot be reformed by better devices alone—only by better accounting joined to better devices.

Preservation of the therapeutic relationship should be treated as a core clinical and design requirement rather than a soft constraint to be traded away. Done with this discipline, digital healthcare can extend the reach, consistency and accessibility of expert FND care without eroding what makes that care effective. If FND—long among the most neglected of the common neurological conditions—becomes the exemplar for building care systems this way, the benefit will extend well beyond FND, to the wider family of chronic, fluctuating disorders with which it shares both mechanism and marginalization.

Ethics. This work did not require ethical approval from a human subject or animal welfare committee.

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Authors' contributions. A.Da.: writing—original draft, writing—review and editing; A.Du.: writing—original draft, writing—review and editing.

Both authors gave final approval for publication and agreed to be held accountable for the work performed therein.

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A.Du. is involved in developing intellectual property with potential commercial application and may therefore have a prospective financial or professional interest in its future development and commercialisation. React2Home is a registered research protocol, discussed here as an illustrative architecture for experience-based co-design, requirements engineering, verification and staged validation, its inclusion should not be interpreted as independent validation, regulatory or commercial endorsement, or evidence of clinical effectiveness. A.Da. declares no competing interests.

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