Funding Friday Series - Episode 4

WHAT "BREAKTHROUGH INNOVATION" ACTUALLY MEANS

REVERSE-ENGINEERING THE EXCELLENCE CRITERION THAT DETERMINES YOUR FUNDING FATE

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The **Excellence criterion** is the gatekeeper of the EIC Accelerator, accounting for 30-40% of your total score. It is also the **primary graveyard for applications**; between 2021 and 2024, **65% of proposals** were **rejected** at Step 1, with an insufficient demonstration of "**breakthrough innovation**" cited as the leading cause of failure.

For European grant evaluators, "breakthrough" is not a marketing buzzword—it is a rigorous evidentiary standard. This episode reverse-engineers the Excellence criterion by analysing two funded champions: **Panntherapi** (biotech therapeutics) and **Mode Sensors** (medical device). We reveal how they navigated the **three pillars of Excellence**: technological novelty, competitive advantage magnitude, and transformative impact potential.

THE THREE PILLARS OF EXCELLENCE

European grant evaluators (e.g. EIC Accelerator) assess **Excellence** through three tightly defined and explicitly scored pillars: **technological novelty,** magnitude of **competitive advantage,** and **transformative impact** potential**.**

PILLAR 1
Technological Novelty

Evaluators distinguish between novel approaches versus modifications of established technologies to address existing problems. The highest-scoring applications demonstrate:

- **State-of-the-art advancement,** represents fundamentally new approach rather than engineering optimisation of existing solutions
- **Scientific originality:** Innovation leverages recent scientific discoveries, novel mechanisms of action, or previously unexplored biological pathways
- **First-in-class positioning:** Solution addresses previously unsolvable problems or enables capabilities impossible with current technologies.

PILLAR 2
Competitive Advantage

Evaluators assess not whether your technology is better, but by how much. The **critical threshold** (e.g. 10-fold) improvement over existing solutions in at least one clinically meaningful parameter. This quantification distinguishes incremental from breakthrough innovations:

- **Performance metrics:** 10× faster detection, 10× higher sensitivity, 10× lower cost, 10× improved patient outcomes
- **Solved vs. mitigated**: Technology solves problems existing solutions merely manage
- **Multiple simultaneous advantages**: Best applications show 3-5× improvement across several parameters simultaneously.

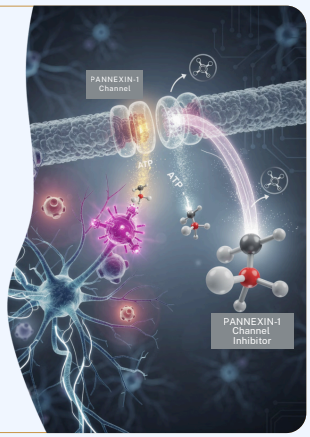
PILLAR 3
Transformative Impact

The highest Excellence scores go to innovations fundamentally changing healthcare delivery, creating new treatment paradigms, or enabling precision medicine approaches.
Evaluators assess:

- **Healthcare system transformation**: innovation that change standard of care, clinical guidelines, or treatment
- **Market creation**: innovations that create entirely new markets or capture a large share of existing one
- **Societal benefit magnitude** with quantified impact on patient quality-adjusted life years (QALYs), healthcare cost reduction, or public health outcomes.

PANNTHERAPI: Technological Innovation Addressing a Gap in Paediatric Epilepsy

- ***Novel Mechanism:*** *First-in-class targeting of pannexin-1 (Panx1) channels—completely unexplored in epilepsy. Conventional anti-epileptic drugs target ion channels (sodium, calcium, GABA), while PTI5803 addresses neuro-inflammation and ATP release pathways implicated in seizure generation and drug resistance.*
- ***Evidence Package:***
  - *Published research: Panx1 up-regulation in epileptic brain tissue*
  - *Preclinical validation: 85% seizure reduction in Dravet syndrome mouse models vs. <30% with conventional AEDs*
  - *Mechanism studies: Proved Panx1 blockade reduces ATP release, neuro-inflammation, aberrant neuronal synchronisation*
  - *Biomarker identification: Enables patient stratification and treatment monitoring*
- ***Why First-in-Class:*** *Only therapeutic targeting neuro-inflammation pathway in drug-resistant epilepsy. Extended-release formulation enabling sustained Panx1 blockade—novel delivery approach for paediatric epilepsy where existing treatments require multiple daily doses. Addresses 150,000 European children annually where existing solutions fundamentally fail.*



Mode Sensors: Creating New Healthcare Markets by Moving Monitoring Beyond the ICU

Problem: €500M ICU-bound CVP monitoring market; reactive care driving readmissions, prolonged ICU stays, avoidable complications
Solution: Continuous, ambulatory haemodynamic monitoring enabling predictive care across wards, home, and outpatient settings
Strategic Advantage: Shifts care model from ICU-centric, reactive treatment to scalable, predictive system-wide monitoring
Proven Impact Per 1,000 Patients:

30-35%	40%	1.2-1.8	€1.6M	3-5x	+0.15-0.22
Fewer HF readmissions	Reduced fluid overload events	ICU stay reduction (days)	annual savings	Return on Investment	QALYs

QUANTIFYING BREAKTHROUGH

Successful applicants **align evidence precisely with evaluator expect** and present quantified **proof of breakthrough** performance. First, the **minimum evidence package** depends on the innovation:

- Medical devices: clinical samples, cadaver or early clinical studies
- Diagnostics: multi-site clinical validation
- Therapeutics: animal models with clear human disease relevance
- Sustainable livestock innovations: controlled field trials

Second, **validation must be executed with regulatory-level rigour**, including predefined protocols, statistical analysis plans, and data quality controls. Evaluators expect quantitative superiority comparable to regulatory submissions:

Medical Devices

- Clinical outcome gains (e.g. ↓ mortality %, ↓ complication rates, ↓ procedure time)
- Health economics impact (cost per QALY, length-of-stay reduction, system-level savings)
- Head-to-head superiority versus gold standard

Diagnostics

- Analytical performance (sensitivity, specificity, PPV/NPV across populations)
- Clinical validation (accuracy, time-to-result, false-negative reduction)
- Demonstrated clinical utility (treatment decisions changed, outcome improvement)

Therapeutics

- Preclinical efficacy (tumour inhibition %, survival benefit, MoA validation)
- Safety differentiation (expanded therapeutic window, reduced toxicity)
- Clearly quantified unmet need (patient numbers, inadequacy of current care)

The defining pattern of funded applications is not data volume, but **data credibility,** such as independently validated results, robust statistics, and documentation approaching regulatory submission quality, with peer-reviewed evidence where possible.

RED FLAGS TRIGGERING IMMEDIATE REJECTION

Analysis of rejected EU grant applications shows predictable failure patterns that raise evaluator concerns during remote assessment. These red flags typically signal immaturity, over claiming, or execution risk.

Technical Red Flags

- Claims without data: "Revolutionary" positioning unsupported by quantitative evidence
- Weak benchmarking: Comparison against outdated or non–best-in-class technologies
- Insufficient validation: In-silico or in-vitro data where in-vivo or clinical evidence is expected
- Unclear mechanism of action: Especially for therapeutics, no convincing target engagement or biological rationale

Commercial Red Flags

- Vague target population: Broad claims (e.g. "cancer patients") instead of defined indications
- Unrealistic timelines: Promising 12–18 months for development paths that typically require 4–5 years
- Regulatory naïvety: Limited understanding of MDR/IVDR or EMA requirements
- No reimbursement logic: Absence of a credible pathway to payer adoption

Team Red Flags

- Purely academic teams: No demonstrated translation, regulatory, or commercialisation experience
- Missing critical expertise: Lack of regulatory affairs, quality systems, or clinical development leadership
- Governance instability: Unclear IP ownership, founder disputes, or unresolved equity structures.

Applications triggering multiple red flags are rarely rescued by scientific novelty and evaluators judge them as incompatible with public funding.

CONCLUSION: FROM ABSTRACT TO CONCRETE

Companies such as **Panntherapi** and **Mode Sensors** succeed because they turn "breakthrough innovation" into hard, quantifiable proof. Their strength lies not only in ambition or narrative, but also in evidence packages that demonstrate true technological novelty, order-of-magnitude **competitive advantage,** and credible potential to transform healthcare or market structures. This is exactly how European evaluators assess Excellence: not by what a company hopes to achieve, but by **what it can already prove** with regulatory-grade rigour. Teams that understand this distinction consistently outperform scientifically strong but poorly evidenced competitors.

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The 19th of December 2025, in Paris.

Wishing you and your loved ones a wonderful holiday season!

You are developing a Life Sciences innovation *and want to know whether it qualifies as* ***breakthrough under EU funding criteria?***

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