

Senior oncology-development judgment for the decision a program turns on next

For founders, CMOs, boards and investors who need to know whether a development and regulatory story will hold up in a board, a financing, or a health authority room — and what it would take to make it hold. A single-operator practice led by Jesús Gómez-Navarro, M.D.

WHERE THE PRACTICE WORKS

The front end of oncology development, where one decision shapes everything after it

Discovery target, candidate	Pre-IND endpoint, population, pre-IND meeting	First-in-human dose, cohorts, what was learned	Phase I expansion next cohort, next financing	Phase II selectively	Late stage declined
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Calibration Sprint Ten business days · fixed fee

Development-path track Is the proposed path defensible?
First-in-human evidence track What do the human data already support?

↓ **WHERE THE WORK CONTINUES**
Fractional CMO · Board director or scientific advisor

The fit call decides the track with one question: what evidence has to carry the answer? A Phase I program can sit in either.

WHO IT SERVES

Three kinds of client, one kind of question

Oncology biotechs
Pre-IND to Phase I, typically after a recent Series A or B, with a real decision due in the next 90 to 180 days.

AI-oncology and platform companies
Companies whose models will eventually inform a regulatory decision, and AI-native developers that acquire or license and sponsor their own assets.

Boards, investors, family offices
Weighing someone else's early oncology program before the next commitment. Scope spans FDA, EMA, PMDA and NMPA.

HOW IT ENGAGES

One entry engagement, two ongoing roles

Calibration Sprint	Entry	One decision, ten business days, a fixed fee. Four written artifacts and a live, adversarial readout. An independent no is as valuable as a yes.
Development-path track		When the answer rests on whether a proposed path is defensible. Calibration Map, Evidence Brief, Board One-Pager.
First-in-human evidence track FIH Diligence Read		When the answer rests on what human data already collected actually support. Gate Read, Scored Diligence Read, Decision Synthesis. Scoped typically to one asset and one decision.
Fractional CMO	Ongoing	Embedded with a small number of companies a year. Reserved capacity and accountability, cash-based with equity added selectively.
Board director or scientific advisor	Ongoing	Where the contribution is judgment and governance rather than execution.

Availability. Not seeking a full-time executive seat. Open to fractional CMO, board and scientific advisory roles in oncology and AI-oncology.

Fixed fee, scoped after a fit call. Declined: late-stage execution, day-to-day medical monitoring, open-ended retainers.

WHAT MAKES IT DIFFERENT

An accountable operator, with AI as the leverage layer

OncAdios is independent of the asset-acquisition thesis, the model vendor, and the capital already committed. Its role is to adjudicate the oncology decision, including a disciplined no, and to stay accountable for the reasoning in the room where that decision is made.

- **The patient is the reason for the work.** The people who enroll in an early oncology trial are not at the table where these decisions are made. Every read asks whether the program is designed to answer the question they were asked to accept the risk for.
- **The outcome that matters.** Meeting an endpoint, approval, adoption and meaningful patient benefit are different claims, and each is stated separately.
- **AI under explicit governance.** Every claim of consequence is sourced; refusal is a valid output; client data is handled under a written data-handling regime.
- **Transportability.** Evidence from one tumor type, modality, population or setting is not assumed to carry into another.

THE RECORD BEHIND IT

Thirty years across Pfizer, Millennium and Takeda

Immuno-oncology Clinical Lead, Pfizer Oncology: tremelimumab from first-in-human through Phase 3, later approved as IMJUDO. VP, Head of Clinical R&D, Takeda Oncology (2011–2020); Takeda's inaugural Distinguished R&D Fellow. Oversaw seven anticancer approvals worldwide, including by the FDA, EMA, PMDA and NMPA.

NINLARO

ADCETRIS

ALUNBRIG

ICLUSIG

ZEJULA

CABOMETYX

EXKIVITY

tremelimumab, FIH to Phase 3 at Pfizer · later IMJUDO

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