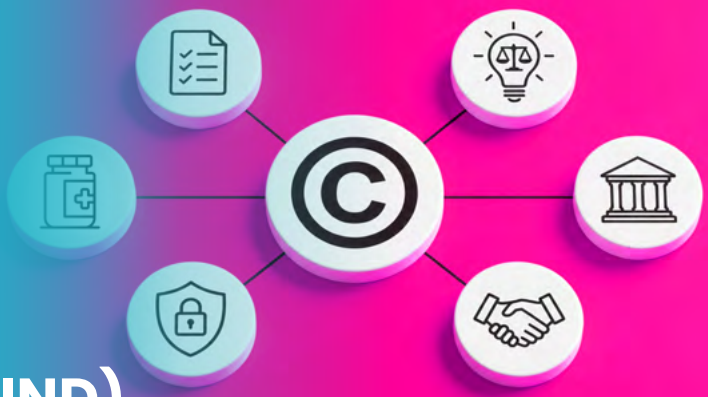
Consultancy:
Insights Series

Building experimental packages that Protect your IP and support your Investigational New Drug (IND)



Every experiment a drug developer runs is read by three very different audiences: the patent examiner, the regulator and a partner/acquirer. Companies that design their data with all three in mind protect more, spend less, reach the clinic faster and do better deals.



Patent examiner



Regulator



Partner/ acquirer

The importance of intellectual property (IP) in the underpinning of a programme/ platform and business strategy is not to be underestimated. A well-structured IP strategy is essential for spin outs, early biotech's and development companies across all their assets. In this article, Rob Docherty, European Patent Attorney and founder of Robin IP, a consultancy specialising in life sciences IP; discuss those considerations that founders and senior teams need to make early. Rob provides his insights relating to how this strategy and data is viewed and interrogated by the various outside parties that use this data to either support or prevent your programme from progressing effectively.

Introduction

In early-stage drug development, experimental data is usually treated as a scientific asset first and a legal asset second. Research teams generate data to answer biological questions; the patent filing is drafted around whatever results happen to exist; and the Investigational New Drug/Investigational (IND) package is assembled later, often by a different team, from the same pool of studies.

This sequence leaves value on the table. The data that convinces a patent office that an invention works is, to a surprising degree, the same data that convinces the FDA that a first-in-human trial is reasonably safe and scientifically justified. The questions differ, but the evidence overlaps.

This article looks at what patent offices and courts now expect from experimental data, what an IND/IMP data package must contain, where the two overlap, and why the same data is central to securing partnerships with larger pharma and biotech companies. It closes with how pharma/biotech teams can plan studies so that one body of work serves all three purposes.



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Why data now carries more weight in patents

A patent disclosing a biopharmaceutical is only as strong as the evidence that the claimed invention works across the scope claimed. Over the past decade, courts and patent offices on both sides of the Atlantic have made that expectation more explicit.



Europe: plausibility and G 2/21. In March 2023 the EPO's Enlarged Board of Appeal issued decision G 2/21. It confirmed that post-filed data can be relied on to support a technical effect, but only if the skilled person, reading the application as filed, would understand that effect to be encompassed by the teaching and embodied by the same invention. For second medical use claims, the bar is higher still: the application itself must make the therapeutic effect credible. A bare statement that a compound "may be useful" against a disease rarely suffices without experimental support in the application as filed.



United Kingdom: Warner-Lambert. The UK Supreme Court's decision in *Warner-Lambert v Generics* [2018] UKSC 56 found second medical use claims to pain invalid for insufficiency because the application did not make the effect plausible across the breadth claimed. The lesson for applicants was stark: claim breadth must be matched by evidential breadth.



United States: Amgen v Sanofi. In May 2023 the US Supreme Court held in *Amgen v Sanofi* that functional genus claims to antibodies were not enabled. The specification disclosed 26 antibodies but claimed a vast genus defined by function. Broad functional claims now need a disclosure that genuinely teaches how to make and use the full scope, not a research plan for finding it.

The common thread is that the **data in the application as filed defines what can be protected.** Data generated later may help but cannot rescue a filing that lacked a credible basis on day one.

What the IND data package must show

An IND application asks a narrower but more demanding question: is it reasonably safe to give this product to humans, at this dose, in this trial design? Typically, an IND package should assess:

Pharmacology and drug disposition: mechanism of action, pharmacodynamic effects in relevant models, and absorption, distribution, metabolism and excretion (ADME) data.

Toxicology: GLP-compliant studies supporting the proposed starting dose, dose escalation and duration of exposure.

Chemistry, Manufacturing and Controls (CMC): identity, composition, purity, stability and a manufacturing process capable of producing consistent clinical material.

Prior human experience, where any exists.

The nonclinical landscape is also shifting. In April 2025 the FDA published its Roadmap to Reducing Animal Testing in Preclinical Safety Studies, starting with monoclonal antibodies. Its stated aim is to make animal studies the exception rather than the norm within three to five years. In March 2026 the agency followed with draft guidance setting out a validation framework for new approach methodologies such as organ-on-chip systems, in vitro assays and in silico models.

This matters for patent strategy. Human-relevant in vitro and computational data will increasingly sit in the IND package, and the same kind of data is exactly what can make a therapeutic effect credible in a patent application.

Where the two overlap, and where they pull apart

Most early-stage data can do double duty. The table below shows how the same study types are read by each audience.

Data type	What it does for the patent	What it does for the IND
In vitro potency and selectivity	Makes the technical effect credible; supports inventive step over prior art	Establishes mechanism and informs pharmacologically active dose
In vivo efficacy in disease models	Supports plausibility of medical use claims, in particular, second medical use claims	Provides proof of concept and justifies the clinical indication
Structure–activity relationship across analogues	Supports breadth of genus claims; fallback positions	Supports candidate selection rationale
ADME and pharmaco-kinetics	Supports claims to formulations, dosing regimens and routes	Required to predict human exposure and set starting dose
Toxicology and safety margins	Can support selection inventions and dosage regimen claims	Core of the safety case; required to support first-in-human dosing
Formulation and stability	Basis for later formulation and process patents that extend lifecycle	Core CMC content
Biomarker and patient stratification data	Supports patient-subgroup and companion diagnostic claims	Supports trial design and enrichment strategy

The tension lies in **breadth versus depth**. Patents reward breadth: data across many compounds, doses, indications and variants supports broader claims. The IND rewards depth: exhaustive, GLP-quality characterisation of one candidate. A programme optimised only for the IND may leave the patent supporting little beyond the lead molecule. A programme optimised only for the patent may generate broad but shallow data that regulators cannot use.

The answer is not to run twice as many studies. It is to design studies so that each yield both: for example, including a representative spread of analogues in an efficacy model, or testing a range of doses that maps onto later claim language.

Timing: when data is generated, and when it is disclosed. The value of data depends heavily on when it exists and who has seen it.

File too early and the application is thin. A priority filing made on a hypothesis and a single assay may not make the claimed effect credible. Under G 2/21, later data can reinforce an effect the application already points to but cannot introduce a new one.

File too late and the data may already be prior art. Conference posters, grant reports, preprints, investor decks shared without confidentiality, and even thesis deposits can all destroy novelty in Europe, which has no general grace period. The United States offers a one-year grace period for the inventor's own disclosures, but relying on it sacrifices protection elsewhere.

Regulatory disclosure is a separate risk. IND submissions themselves are confidential, but clinical trial registrations, investigator brochures circulated to sites and publications from early trials all put information into the public domain. Formulation, dosing and patient-selection inventions arising from the clinical programme need to be captured before that happens.

The practical model is a staged filing strategy: a priority application on credible early data, strengthened within the 12-month priority year as more data arrives, then further applications on selection, formulation, dosage regimen and biomarker inventions as the IND-enabling and clinical work generates them. Each layer is supported by data that the development programme needed anyway.

Data as the currency of partnerships. For most startups the route to market runs through a partnership with a larger pharma or biotech company. In those negotiations, the data package is what is really being bought: the patents define what the partner can exclude others from, and the data shows whether that exclusivity is worth having.

Partners diligence patents and data together. A business development team will ask whether the claims cover the product they intend to develop, how much patent term remains at expected launch, and whether competitors can design around. They will then ask whether the underlying science holds up. Large companies have learned to be sceptical: in a widely cited 2012 Nature commentary, Amgen scientists reported confirming the findings of only 6 of 53 landmark preclinical studies. Robust, well-controlled, reproducible data is therefore a negotiating asset.

Value steps up at data inflection points. Deal terms, from upfront payments to milestones and royalty rates, typically track de-risking events: in vivo proof of concept, candidate nomination, completion of IND-enabling studies, and early clinical proof of mechanism. Each is a data event. A company that can show both a credible IND path and patent claims supported by the same evidence negotiates from a stronger position than one that offers either alone.



Regulatory exclusivity sits alongside patents. Partners model total exclusivity, not patent life alone. Regulatory data protection, such as 12 years for new biologics in the US (42 U.S.C. § 262(k)(7) (Public Health Service Act § 351(k)(7)) and the 8+2(+1) regime in the EU (Directive 2001/83/EC, Article 10(1), as amended by Directive 2004/27/EC), runs from approval and depends on the regulatory dossier the data supports. A clear picture of both forms of protection makes the asset easier to value.

Data rights must be negotiated, not assumed. Collaboration, option and licence agreements should state who owns data generated during the partnership, who may use it in regulatory filings and to support patent applications, how improvements and new inventions are owned, and what each party may publish. Poorly drafted data clauses are a common source of later disputes and can leave a startup unable to use its own results if the deal ends.

A well-organised data room shortens diligence. Study reports, raw data, lab records, inventorship records and confidentiality agreements, organised to tell one consistent scientific story, signal a well-run company and remove friction from the deal timetable.

Sources

- EPO Enlarged Board of Appeal, G 2/21 (23 March 2023)
- Warner-Lambert Co LLC v Generics (UK) Ltd [2018] UKSC 56
- Amgen Inc v Sanofi, 598 U.S. 594 (2023)
- 21 CFR 312.23, IND content and format.
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- FDA, New Approach Methodologies, including draft guidance General Considerations for the Use of New Approach Methodologies in Drug Development (March 2026)
- Begley CG and Ellis LM, "Raise standards for preclinical cancer research", Nature 483, 531–533 (2012)
- 42 U.S.C. § 262(k)(7) (Public Health Service Act § 351(k)(7)
- Directive 2001/83/EC, Article 10(1), as amended by Directive 2004/27/EC

Practical playbook for startup teams

1. Bring IP and regulatory into study design, not just study review. A short conversation before an efficacy or tox study is commissioned costs little and can add claim-supporting arms at marginal cost.
2. Map the claims you want to the data you need. For each intended claim, from compound to medical use to dosage regimen, ask what evidence would make it credible to an examiner, and whether the development plan will produce it.
3. Test more than the lead. Including representative analogues or variants in key assays supports genus claims and provides fallback positions if the lead fails.
4. Keep records that work in both worlds. Dated, attributable, well-controlled data serves GLP expectations and supports inventorship, priority and evidence in later disputes.
5. Control disclosure. Run publications, posters, grant reports and investor materials past IP counsel. Use confidentiality agreements with CROs and partners as standard.
6. Plan the filing around development milestones. Align patent filings with candidate selection, IND-enabling studies and first-in-human, so that each new layer of data becomes a new layer of protection.
7. Treat the data package as a deal asset. Investors and licensees diligence patents and regulatory readiness together. A coherent story, in which the patent data and the IND data tell the same scientific narrative, is markedly more valuable than either alone.

Conclusion

Patent examiners and regulators ask different questions, but they read the same experiments. Recent case law has made credible experimental support the price of meaningful patent protection, while the FDA's move towards human-relevant methods is reshaping what an IND data package looks like. And when a larger partner comes to the table, it is that same body of evidence that sets the value of the deal. Companies that plan their data with all of these audiences in mind protect more of their innovation, avoid costly gaps, and present a single, coherent story to regulators, investors and partners.

The best time to have that conversation is before the next study is commissioned.

Robin IP

Robin IP Limited is a York/UK-based boutique consultancy providing life sciences IP strategy and management, from start-ups to established pharma and biotech. Its core services are:

1. **IP Strategy & Audits:** commercially aligned strategies that map assets and identify gaps.
2. **Patent Drafting:** filing-ready applications, prepared alongside the client's attorneys or trusted prosecution partners.
3. **Portfolio Management & In-House Fractional IP Counsel** including global portfolio strategy & budgeting.
4. **Due Diligence:** for investment, acquisitions and licensing.

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