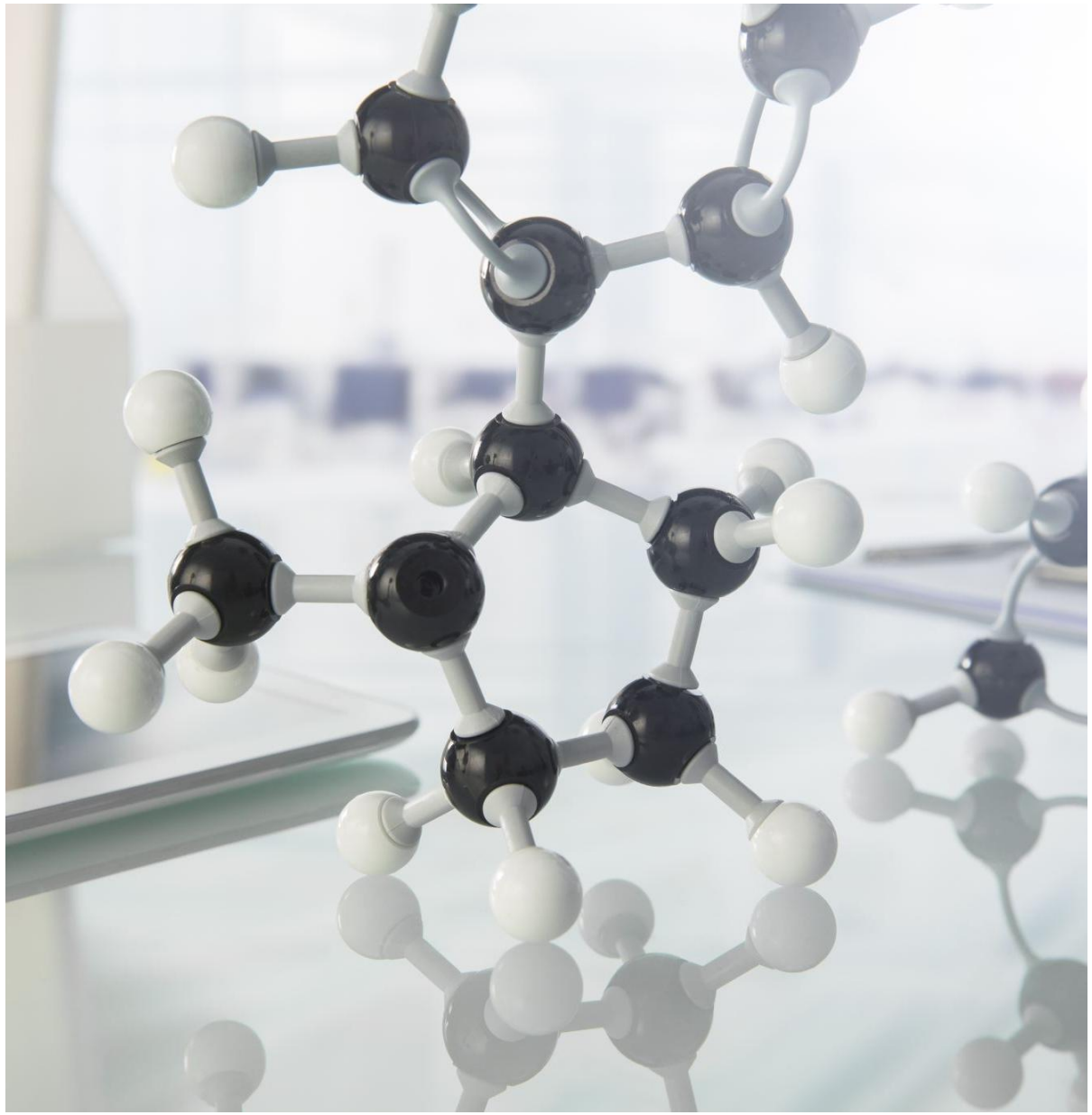
PatrickToxConsulting

Nonclinical Toxicology Expertise

Tailored toxicology consultancies for start-up, biotech, pharmaceutical companies and CROs preclinical programs



Agenda Items

Introduction to PatrickToxConsulting

About Patrick SYNTIN

Services Offered
- Nonclinical development plan preparation
- Subcontracting activities
- Toxicology expertise:
  - *Target safety assessment, Impurity qualification or Due diligence*
- Regulatory dossier redaction
- Interaction with health authorities

Areas of Expertise
- Biological products
- Vaccines (including mRNA & adjuvants)
- Small molecules

Why Choose PatrickToxConsulting?

Introduction to PatrickToxConsulting

Nonclinical toxicology expertise

PatrickToxConsulting

Welcome to PatrickToxConsulting, a full-service toxicology consulting firm established in 2025 by Dr. Patrick SYNTIN, a preclinical safety consultant.

“As an experienced toxicologist expert, I provide evaluations of preclinical candidates, recommendations on development programs and de-risking strategies to prepare for clinical trials or registration.

My clients are typically start-ups, biotech, MedTech, pharmaceutical companies and CROs developing biological products, small molecules, chemicals, medical devices or vaccines.

Services can include:

- *Identification of preclinical development candidate risks,*
- *Design of nonclinical development plans,*
- *Identification of CROs and study monitoring,*
- *Review of data and risk management,*
- *Preparation of regulatory dossiers (nonclinical safety sections),*
- *Interaction with health authorities,*

at all development stages from early candidates to registration.

Patrick SYNTIN, PhD., ERT Toxicology consultant

Educational Background

Patrick SYNTIN holds a PhD in Reproductive Physiology and is a European Registered Toxicologist (ERT). With over 25 years of experience in toxicology, he brings a wealth of knowledge to the field.

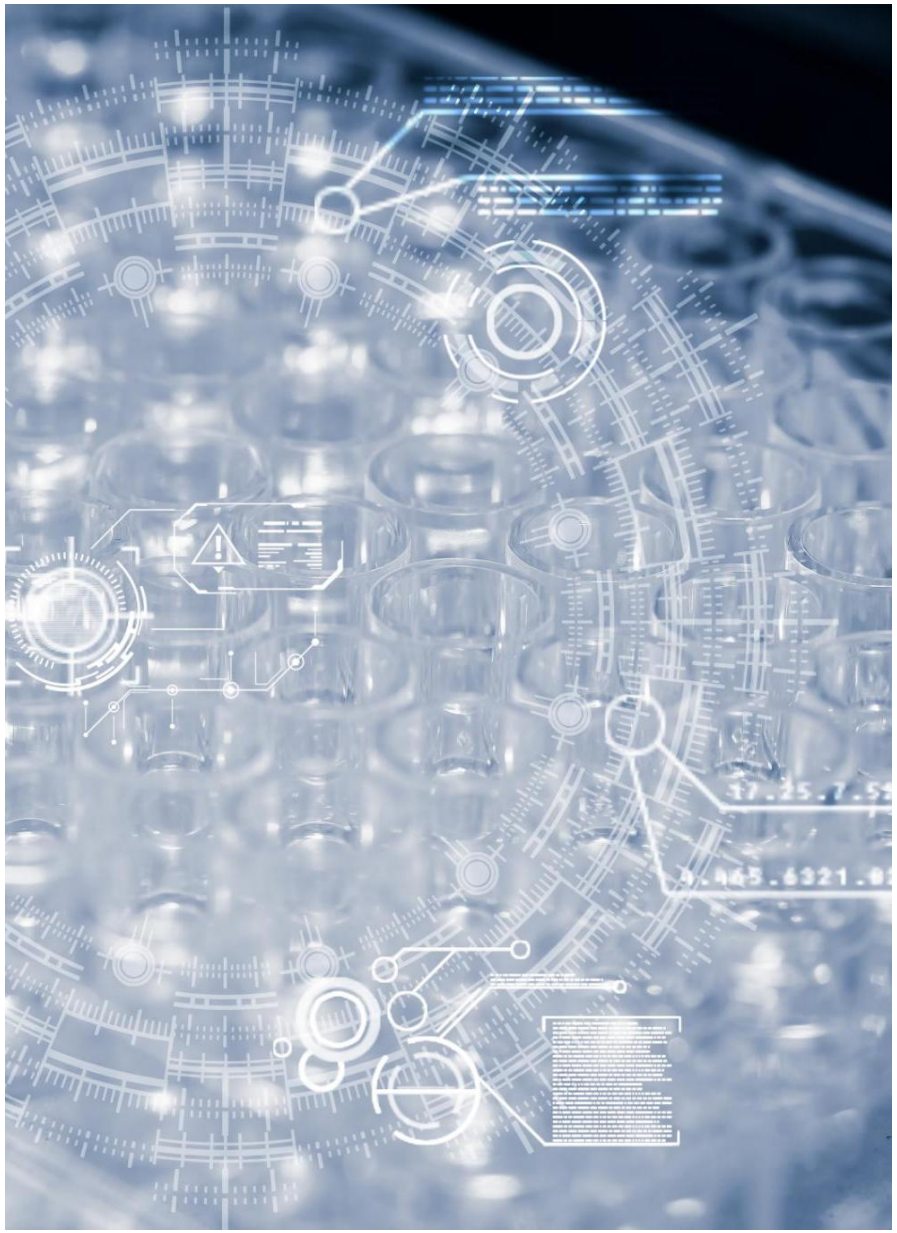
Vast Experience in Large Pharmaceutical Companies

Patrick has held various positions as study director, project team member and toxicologist expert, including:

- 1 year at **CIT**: Study direction in the context of a CRO
- 7 years at **Pfizer**: Toxicology expertise (Pain, Sexual disorder, Inflammatory Bowel Diseases, Metabolic diseases, Infectious diseases)
- Over 1 year at **Novartis** in Siena: Toxicology expertise (Vaccines and Adjuvants)
- 7 years at **Pierre Fabre**: Toxicology expertise (Oncology, Medical device, Dermatology, Herbal medicinal products, Food supplements)
- 9 years at **Sanofi**: Toxicology expertise (Vaccines, including mRNA-LNP, and Adjuvants; Pharmaceutical products for Infectious diseases and Biological products in Immunology and inflammation).

He has a solid experience of preclinical safety in major pharmaceutical companies, and of multiple product modalities, ensuring a recognized expertise and high quality of consulting services.

Services Offered



Strategic support to prepare optimized development plans

Solid knowledge in preclinical development

Patrick has acquired a strong knowledge in preclinical development (from early stages up to marketing and life cycle management) through exposure to various domains including:

- New chemical entities (in various therapeutic areas),
- Biological products (such as monoclonal antibodies, bi- or tri-specifics, antibody drug conjugates or peptides),
- Chemical products,
- Food supplements,
- Herbal medicinal products,
- Medical device,
- Vaccines (including mRNA-LNP vaccines) and adjuvants.

Detailed Nonclinical Development Plans

Patrick prepares comprehensive development plans tailored to project goals, client needs, product specifics, indication and targeted countries in line with the most up-to-date regulatory guidelines.

Subcontracting

Extensive experience in toxicology study design

Patrick has designed and conducted numerous preclinical toxicology studies under GLPs at various CROs. Studies ranged from acute to chronic in various animal species (including rodents, dogs, NHPs, minipigs, rabbits, etc…) through various route of administrations. Specialized studies have included for instance immunotoxicity and teratology studies as well as *in vitro* studies (to assess genotoxicity, local tolerance) and compatibility packages.

Monitoring support and Timely project execution

Patrick will negotiate quotes with CROs and propose the best option. He will collaborate with study directors on protocols, ensure monitoring, and conduct audits as needed. Patrick will review data with CROs before report finalization.

By handling logistics, Patrick will manage timelines effectively, ensuring that all subcontracted work is completed within the required deadlines.

Preparation of nonclinical regulatory dossiers

Comprehensive Dossier Preparation

Patrick assists clients on best regulatory pathways and compiles detailed preclinical dossiers covering safety pharmacology, genetic toxicology and animal toxicology data, and other essential elements for regulatory submissions to health authorities.

Patrick prepares nonclinical safety sections for IB, PreIND & IND, IMPD & CTA, sections 2.4 and 2.6 of CTDs, BLAs, NDAs, & MAAs.

Seamless Product Development

Accurate documentation and regulatory support are vital for effective product development. Patrick ensures that all preclinical documentation is prepared accurately and thoroughly.

Interaction with Health Authorities

Nonclinical Safety Dossier support

Patrick promotes nonclinical safety dossiers to ensure compliance during regulatory reviews, minimizing delays in approval.

Addressing Regulatory Questions

Patrick prepares efficient answers to questions raised by health authorities during reviews to alleviate concerns.

Facilitating Approval Processes

This approach should facilitate smoother and more efficient approval processes, enhancing the likelihood of successful outcomes.

Toxicology Expertise

Impurity qualification

Other toxicology expertise include qualification of impurities, residual solvents or E&L in new Drug Substances and Drug Products according to ICH Q3A(R2), Q3B(R2), Q3C(R9) and Q3D(R2) guidelines. It can include permitted daily exposure determination based on data available and/or literature.

Target safety assessment - Bibliographic review

Patrick assists clients in developing robust strategies, including their target safety assessment, risk assessment, and regulatory pathways, enabling informed decisions as they advance.

Due diligence

Patrick provides evaluation of the nonclinical data available for any given due diligence.

Areas of Expertise

Biological products (mAbs, Bi-specifics, ADCs, or peptides)

Main goals of safety evaluation are:

(1) to identify an initial safe starting dose, (2) to identify potential target organ toxicity and their reversibility and (3) to identify safety parameters for clinical monitoring.

Development plans need to be adapted

According, at least, to ICH S6 (biotechnology products), and ICH S9 (for oncology products) as well as EMA (FIH trials, 2007). Main specificities include species selection (toxicology studies should be conducted in a pharmacology relevant species, as such only one species could be accepted), study design and duration, immunogenicity (ADA), reproductive toxicity and carcinogenicity.

Starting dose selection for First in human

Various approaches could be elaborated based on NOAEL, HED, MRSD (as per FDA 2005) or MABEL (EMA, 2007).

Vaccines

Main goals of safety evaluation are:

(1) to support entry into clinical trials (and registration), (2) to identify unexpected toxicities and (3) to identify safety parameters for clinical monitoring.

Nonclinical safety packages for vaccines

According to WHO (2005 & 2013) it should include evaluation of local tolerance, systemic toxicity, and reproductive toxicity.

mRNAs

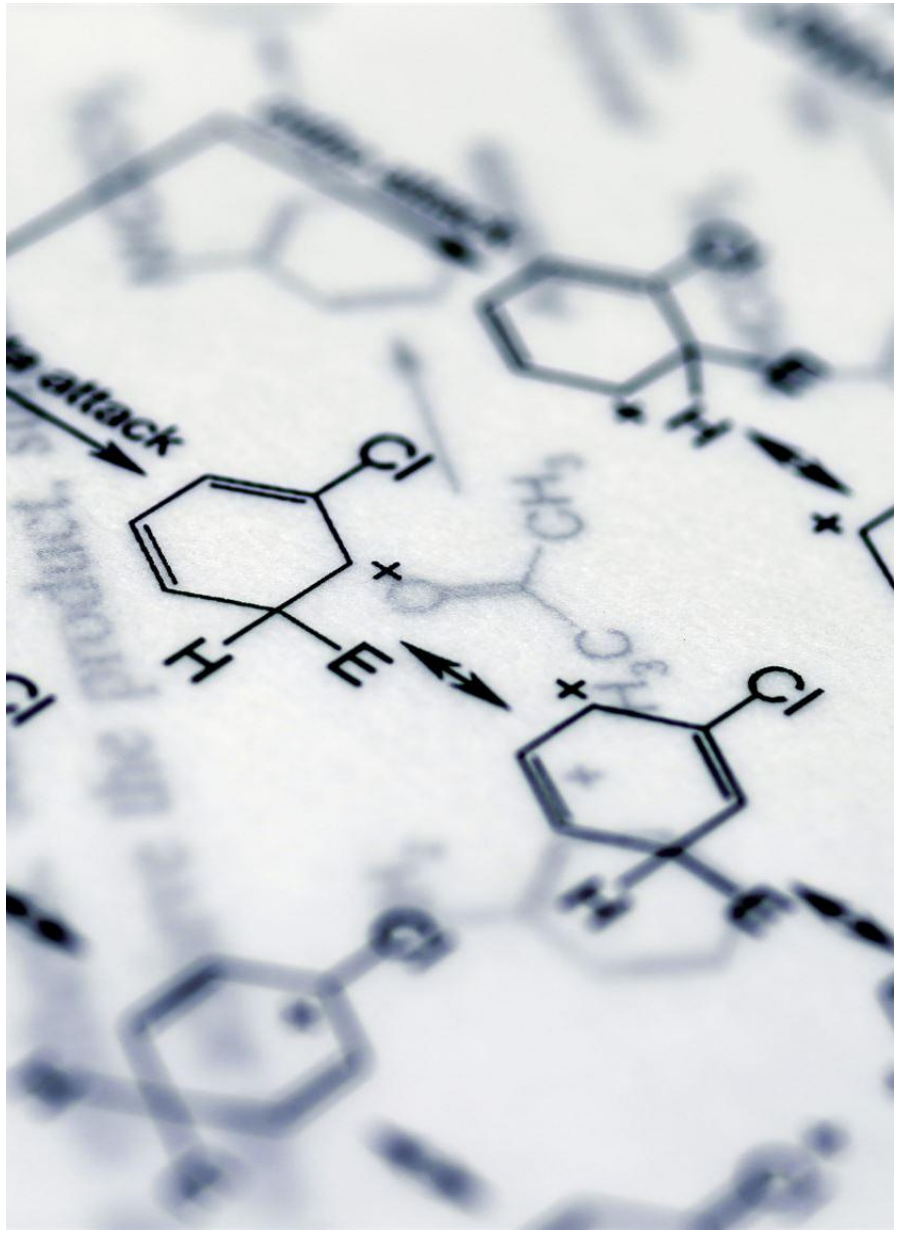
Nonclinical package prepared according to WHO (2021).

Biodistribution studies are performed on a per-product basis.

Toxicology studies need to be conducted in a relevant animal model (immunogenicity to be confirmed), and study designs are adapted based on clinical plans (i.e. schedule of administration).

Adjuvanted vaccines

Nonclinical safety package may need to be extended with safety pharmacology studies and genotoxicity assessments for instance.



New chemical entities (NCE)

The main purposes of toxicological assessments are:

(1) to characterize the toxicity profile of any NCE, with identification of target organs and the potential to induce these effects,

(2) to evaluate the risk by determining if they can occur in humans (based on PK, metabolism, or species specificity) and to assess whether the risk is acceptable (given the indication or the novelty of the approach) and lastly

(3) to manage the risk by identification of safety parameters for clinical monitoring or contraindication recommendation.

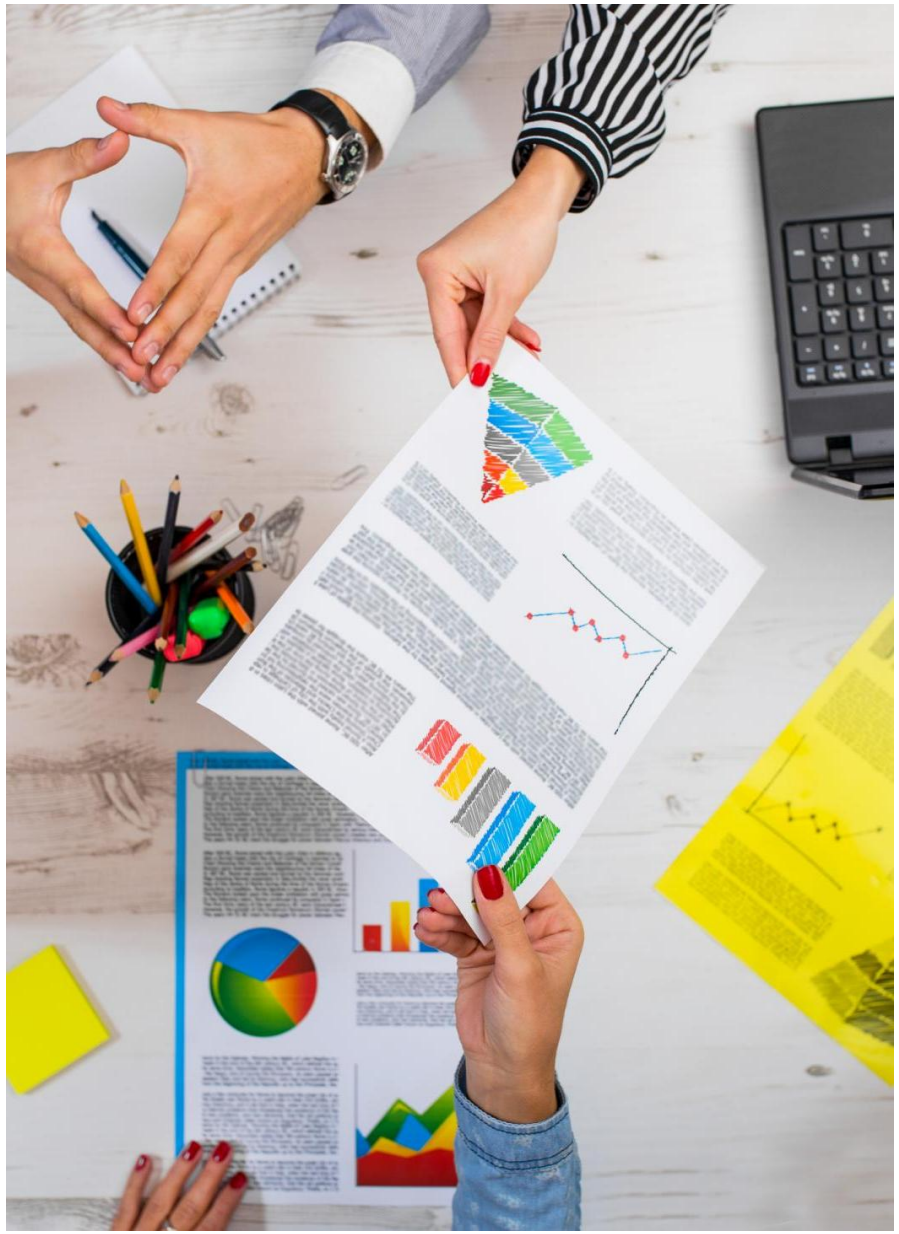
Regulatory environment

Most appropriate nonclinical safety packages will be proposed considering up-to date guidelines from ICH & EMA, FDA, OECD, as well as GLP, ethic principals and 3R rules (including for instance ICH S7, ICH S9, ICH M3, ICH M7 etc…). It will include all required safety pharmacology, toxicology and genotoxicity studies. Additional studies could be recommended on a case-by-case basis including dedicated local tolerance, immunotoxicity, photosafety or juvenile toxicity studies for instance.

Determination of safety margins

Based on efficacy, toxicology and pharmacokinetic data obtained, safety margins could be derived and support FIH entry dose.

Why Choose PatrickToxConsulting?



Unique Value Proposition

Deep Toxicological Knowledge

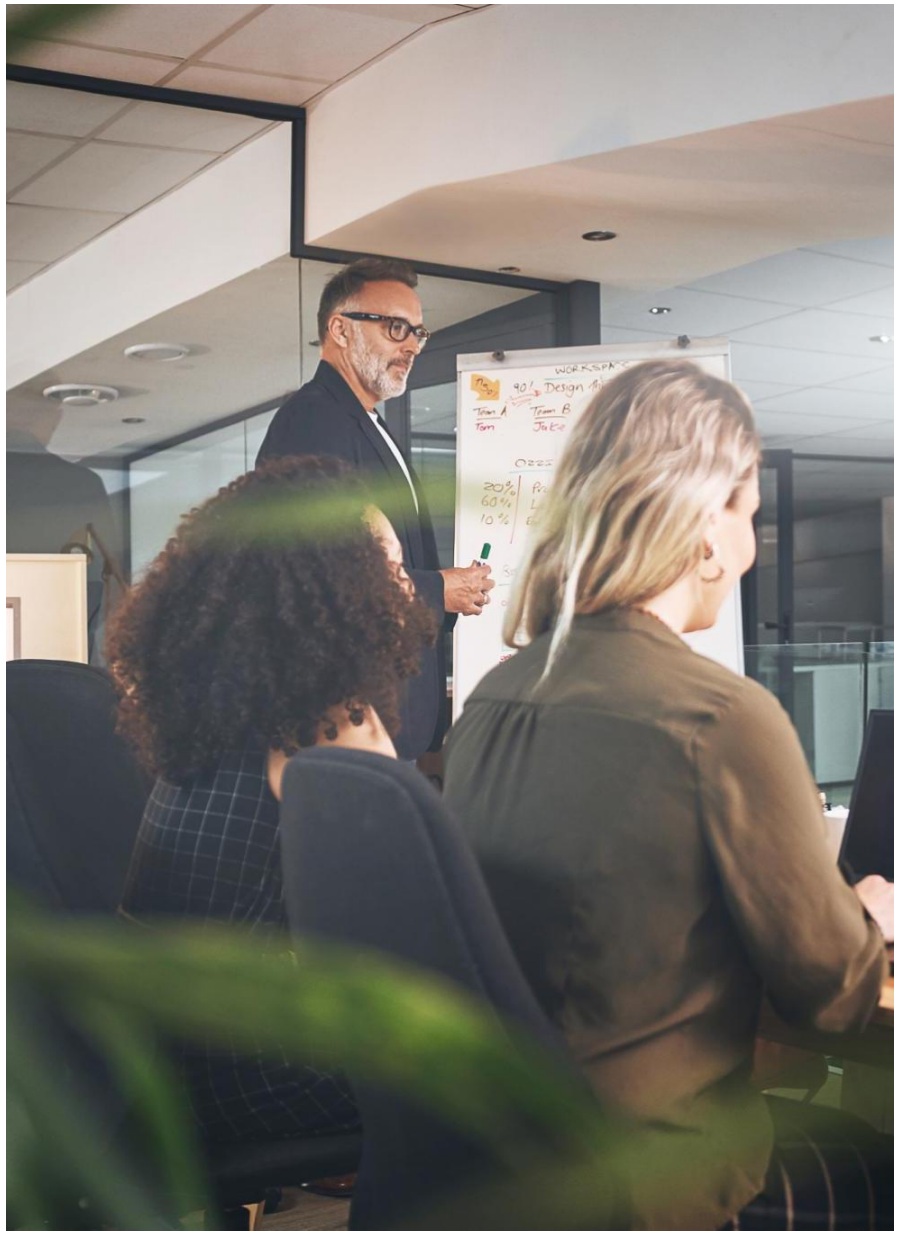
Patrick possesses extensive expertise in all preclinical development stages from research up to registration, in the design and placement of preclinical studies and in preparation of regulatory files.

Personalized Services

Patrick offers a broad array of regulatory consulting services, including strategic regulatory planning for the development, monitoring of toxicological studies, preparation of regulatory dossiers and defense with health authorities or any other toxicological expertise required.

Conclusions:

In conclusion, PatrickToxConsulting is dedicated to delivering expert toxicological services that drive success of your drug development. I invite you to collaborate with me on your next project and experience the value I can bring in it.



Contact your toxicologist consultant

Encouragement to Reach Out

I invite potential clients to reach out for more details and collaboration opportunities. A quotation will be provided in a timely manner.

Contact Information:

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Next Steps to Engage

Clearly outlined next steps will guide clients on how to engage with me effectively to fulfill their needs.


PatrickToxConsulting
Nonclinical Toxicology
Expertise


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Expertise
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Nonclinical dossier preparation; Subcontracting support
Design of development plans; Toxicology assessments