

Proven partner for success

Strengthening Our
Partnership Further

Who are we?

Established in 2013, PCL is formed of a team of highly experienced regulatory experts with over 200 years experience collectively, with a wide network of allied specialists across the globe.

Complete Regulatory Affairs Services

- Team of Regulatory Experts
- Assigned dedicated regulatory experts to Client
- Extensive and global experience
- Regulatory project management – part of in-house teams
- Non-Clinical, Clinical and CMC
- Experience in NCE, biologics and Generic products as well as rare disease products/portfolio

WIDER team with specific expertise

- Agile associate model
- Network of local experts
- Partner companies

200+

Years Combined
Experience

13+

Years Serving
Clients

Global

Regulatory
Reach

Our Operational Model

Delivering Success Through Agility & Precision

01

Structured Yet Flexible

We operate with a structured yet flexible model, ensuring regulatory compliance while remaining adaptable to evolving market needs.

02

Embedded Teams

Our dedicated teams are embedded within the client's regulatory framework, enabling real-time responsiveness and strategic alignment.

03

End-to-End Lifecycle

We provide end-to-end labelling lifecycle management, from gap analysis and risk mitigation to submission readiness and post-approval maintenance.

04

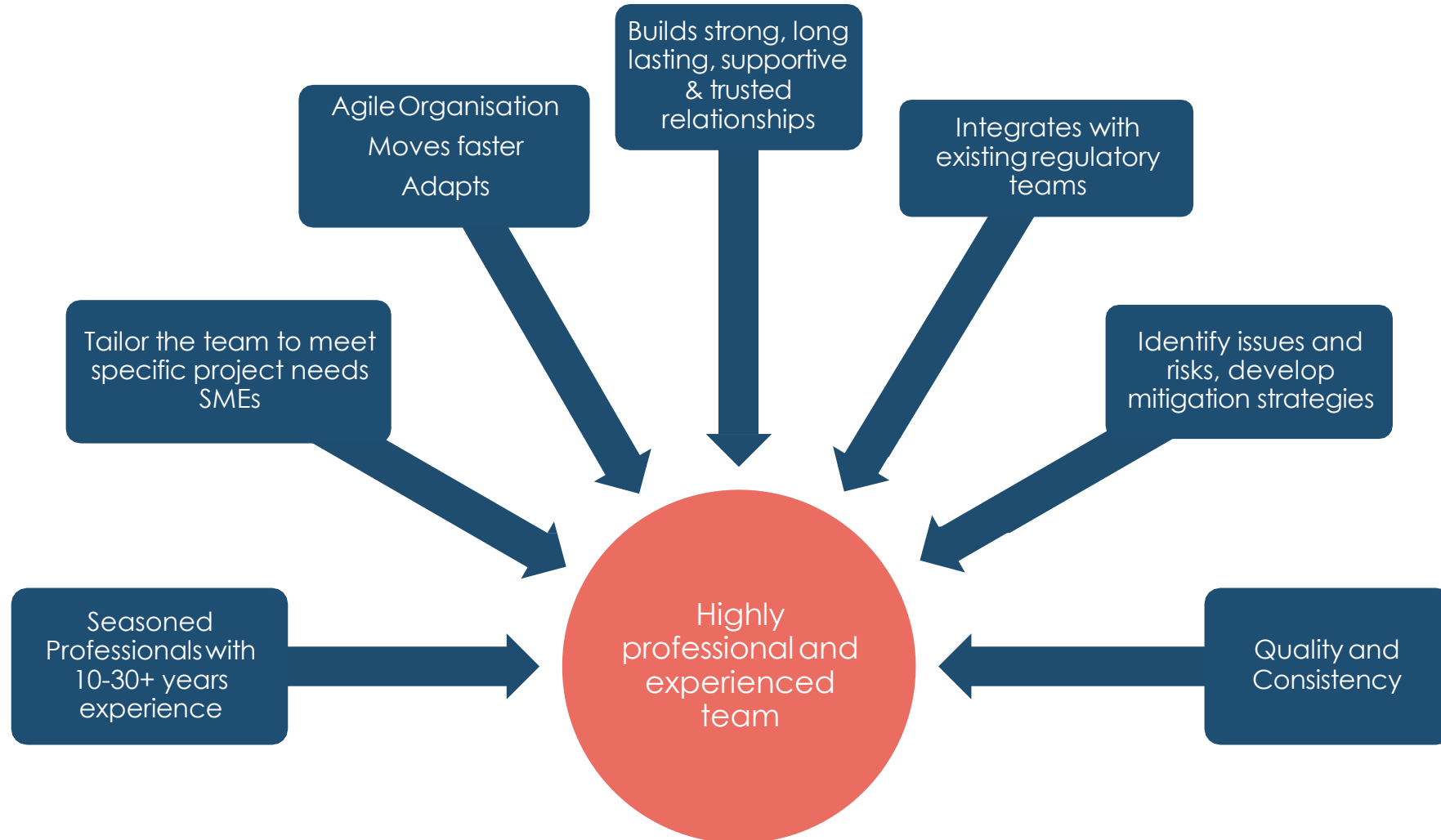
First Time right approach

A first-time-right methodology, we enhance accuracy, efficiency, and compliance across all RA and labelling specific updates.

PCL provide an efficient, quality based response to urgent all RA services including urgent labelling changes that are completed ahead of deadlines • Market-specific alignment without supply chain disruption • Pre-inspection readiness strengthening audit outcomes

How our structure works

Agile, experienced global organisation leads to an effective team



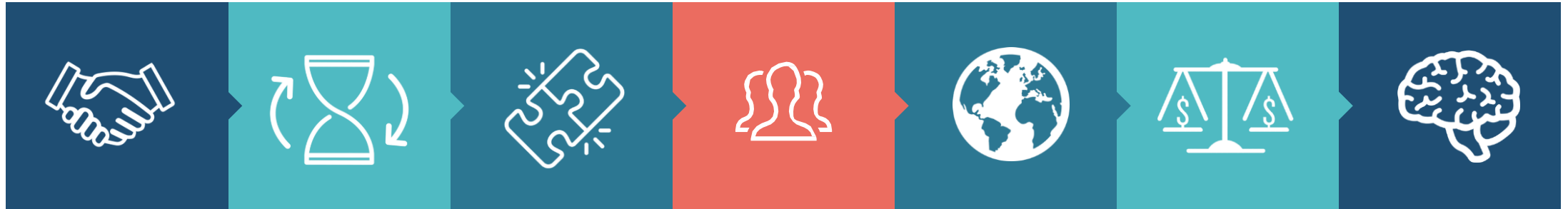
Why clients select PCL

Partner not provider

Custom fit

Global Reach

Innovative strategic thinking



Adaptability

Boutique service,
highly experienced
consultants

Competitive pricing

Services Overview

PCL specialises in providing expert regulatory advice globally to a range of small, medium, and large clients.



Strategic Services

- ✓ Global Regulatory Strategy
- ✓ Target Product Profiles
- ✓ Risk Registers
- ✓ Guidance Documentation
- ✓ Early Access Schemes
- ✓ SME Support
- ✓ Due Diligence



Development Support

- ✓ Agency Meetings
- ✓ Scientific Advice
- ✓ Briefing Documents
- ✓ Paediatric Investigational (Study) Plans (PIPs, PSP's)
- ✓ Orphan Drugs
- ✓ Clinical Trial Applications



Regulatory Affairs Support

- ✓ National, Mutual Recognition, Centralised & Decentralised Applications.
- ✓ Global Product Life Cycle Management
- ✓ PIL User Testing & OTC's
- ✓ Publishing and Redaction



Operational Improvements

- ✓ Departmental Evaluation and Restructuring
- ✓ Mentoring
- ✓ In-house training
- ✓ Regulatory Policy and Intelligence

Development Lifecycle

Phase I

Phase II

Phase III

MAA/BLA/NDA

LCM



EU & Global Regulatory Affairs Capabilities

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- EU Regulatory Affairs Capabilities

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Interaction with European & National Health Agencies

Full support with development & marketing in the EU, USA & ROW

Communication with EMA, FDA & National Agencies (PMDA, ANVISA, BfARM)

Privileged relationships with regulators

- ✓ MAAs collaborations
- ✓ ODDs reviewed/submitted
- ✓ CTA submission management
- ✓ PIPs
- ✓ Scientific Advice procedures
- ✓ CE-marking technical filing
- ✓ Variations and amendments to marketing authorisations

EU Representative for non EU-based companies

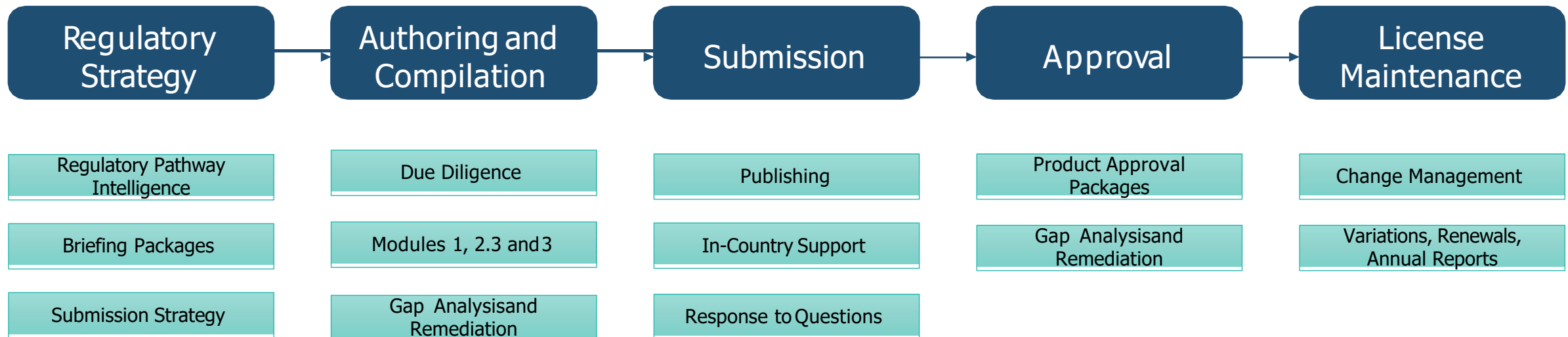
- ✓ Sponsor for ODDs
- ✓ Representative for Small- and Medium-sized Enterprises (SME status)

Advice from EMA, National Agencies & HTA Bodies

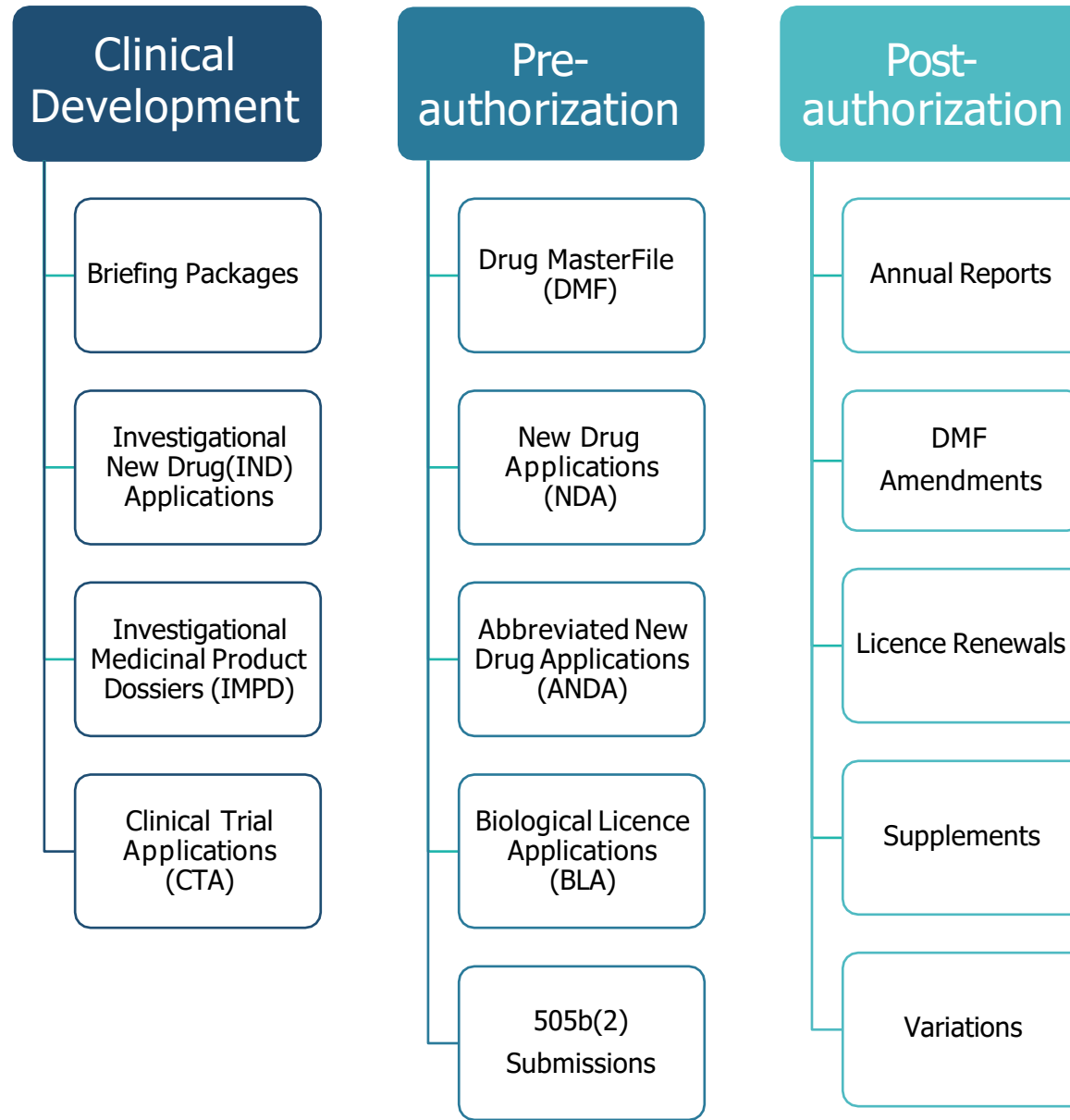
- ✓ EMA or national Scientific Advice
- ✓ EMA-FDA parallel scientific advice
- ✓ Parallel advice from regulators and payers
- ✓ PRIME



BLA/MAA/NDA End-to-End Services



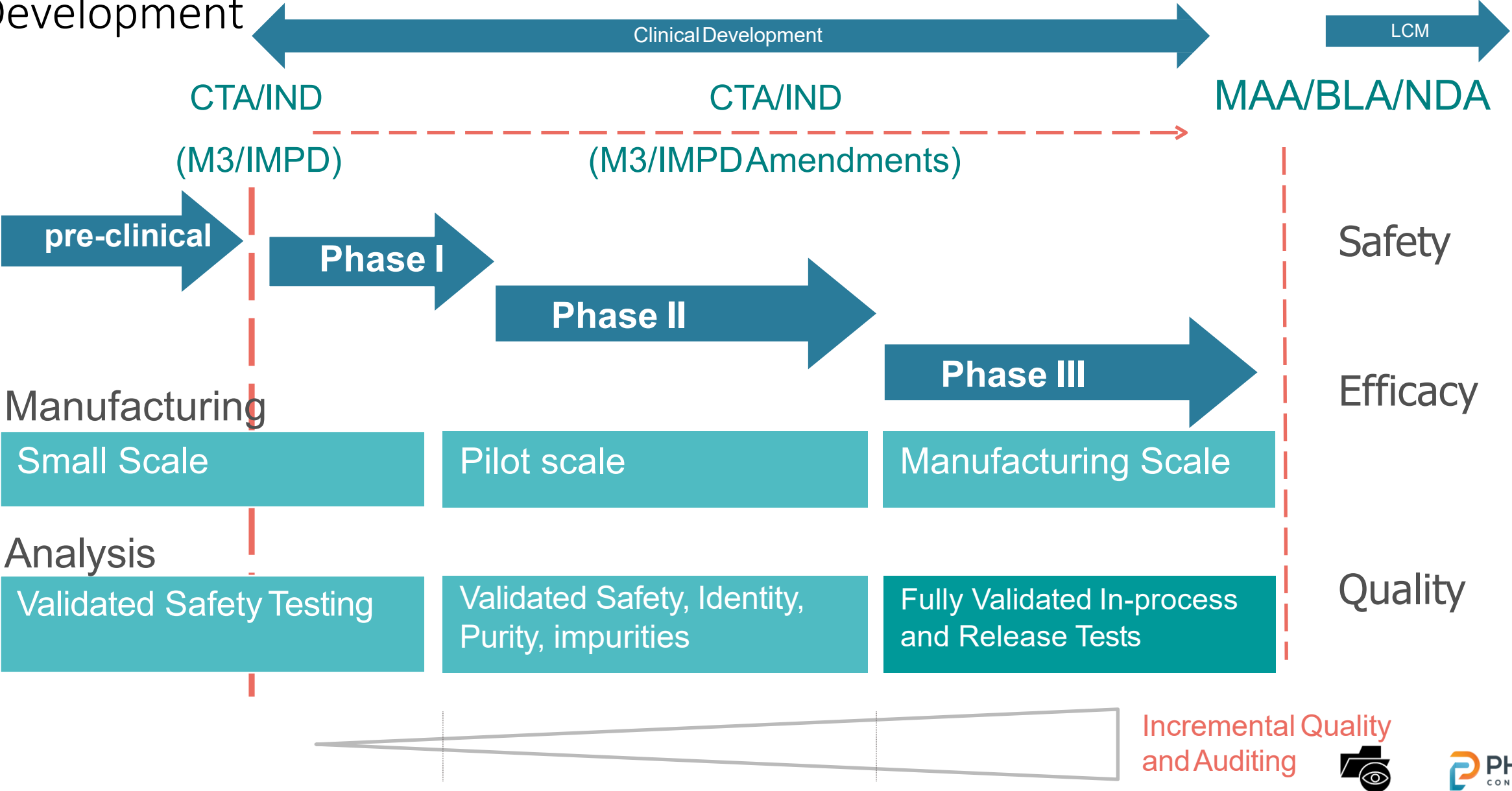
CMC Capabilities - Hands-on industry experience of development, manufacturing, clinical testing, registration & launch



Global : Our CMC experts in the US and EU have the ability to address CMC development to cover requirements from both the FDA and European Health Authorities

Interface : between technical and regulatory aspects of CMC.

Expertise in Overall CMC & Quality Challenges Throughout Product Development



Labelling Services

Product extension/ new acquisition

Identify CSI/
CCDS and
harmonise
CCDSs (transfers
only)

Identify CLD
between the
CCDS and other
existing labels.

Conduct risk
assessment &
synchronise
pending variations
& document
deviations.

Evaluate local
requirement,
labelling standard
and best industry
practices.

Co-ordinate
CCDS draft,
supporting
documents and
local labels.

Present final
drafts to GLC and
escalate for
approval.

Dispatch
submission
packages to
affiliates for
submission.

Translation

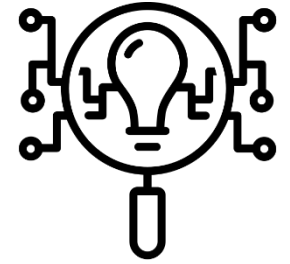
Documents sharing.

Regular meetings and project
status.

Progress update.

Timely execution.

Regulatory Intelligence



New Opportunities e.g.

- Split Real Time Application Review (STAR) program
- Major changes in the UK post BREXIT including review procedures and enhanced access to global markets via Access consortium
- Utilisation of alternative data sources e.g. RWE

Pending Legislation e.g.

- Major updates being reviewed in the EU
- Leaner drug authorization process. Reduction in number of committees
- Speed up review timelines: Current average time from submission to authorization in Europe is 400 days.
- Shortening the period of regulatory exclusivity from 10 years to eight for most medicines.
- Extensions possible if they launch in all EU member states, address diseases with unmet need, conduct comparative trials or launch drugs that treat multiple diseases.

Our Focus Delivers an Actionable Management Strategy

Program Portfolio Design

- Conduct assessments to identify gaps and opportunities for improvement
- Develop a customized portfolio design aligned with strategic objectives and budget
- Utilize industry best practices and regulatory standards to ensure compliance

Program/Project portfolio Management

- Provide project management services to oversee program implementation
- Facilitate communication and collaboration among stakeholders
- Monitor progress and adjust program components as necessary
- Mitigate risks and address issues in a timely manner

Portfolio Reporting/Governance

- Develop customized reporting tools and dashboards to track KPIs
- Analyze data and provide insights to drive decision-making
- Provide regular updates to stakeholders and senior leadership
- Ensure transparency and accountability throughout the program lifecycle

Why We Are the Strategic Partner of Choice

Trusted by Global Leaders — Future-Ready for Success

1

Preferred Partner

Beyond our longstanding relationships, we are the preferred labelling partner for leading global pharmaceutical organisations.

2

Trusted Collaborator

Our ability to scale, adapt, and deliver across diverse regulatory environments makes us a trusted, long-term collaborator.

3

Future-Ready

We are investing in AI and technological innovations to future-proof labelling strategies, ensuring efficiency and compliance at scale.

4

Full Spectrum

Our expertise extends across RX, OTC, and specialty medicine portfolios, positioning us as a full-spectrum labelling solutions provider.

Strategic Partner

Increase in Operational Efficiency with a primary focus on efficient delivery with quality and strategic output

Reduction in error for Regulatory submissions

Reduction and Improved Data Accuracy, Enhancing Regulatory Submissions

Seamless project delivery

Audit Readiness, Ensuring Proactive Compliance Across Global Markets

Thank You

We look forward to partnering with you

Pharma Consultants Ltd | www.pharmaconsultantsltd.com |
info@pharmaconsultantsltd.com