DIAMOND
PHARMA SERVICES

REGULATORY ♦ PHARMACOVIGILANCE ♦ COMPLIANCE

DEVELOPMENT STAGE REGULATORY SUPPORT

The Regulatory Development Department at Diamond Pharma Services has extensive experience in assisting companies to navigate through clinical development. We provide a wide range of services including:

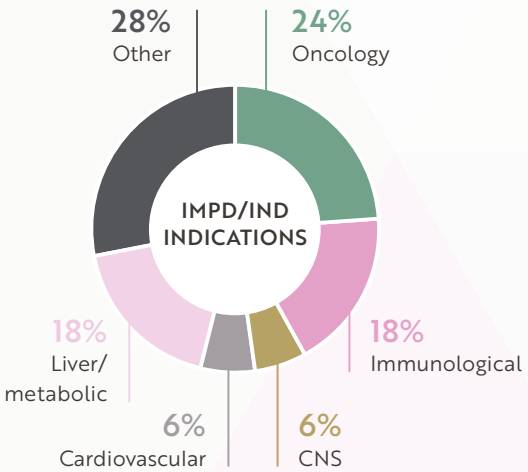
- Regulatory GAP analysis and development plans
- National and EMA scientific advice meetings
- Prime applications
- Orphan designation applications
- Paediatric investigation plans
- CTA
- MAA
- eCTD submissions

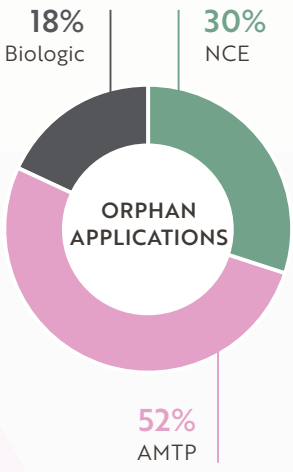
We are specialists in providing bespoke cover to companies either via the provision of dedicated full time equivalent coverage, or ad hoc support. The team have extensive experience in working with Sponsors to write associated dossiers including:

- Briefing documents
- Investigational Medicinal Product Dossiers (IMPD)
- Investigational New Drug applications (IND)
- Investigator's Brochures (IB)

Our staff are experts in liaising with Clients and their CRO/ CMOs to extract the information necessary to write dossiers from source documents.

STATISTICS





OUR CASE STUDIES

Scientific Advice:

- Non-EU small biotech company planning to include EU sites in a Phase II study and building out an EU regulatory pathway to MAA.
- Existing data interrogated, gaps identified and an interim regulatory strategy defined.
- Briefing documents generated from source information.
- National Scientific Advice taken in three countries.
- Clear path to CTA defined (for which Diamond provided further support).
- Follow up regulatory strategy and support provided for more than 5 years, including the provision of interim regulatory director cover.

Interim Regulatory Development Director:

- Small/virtual (bio) pharmaceutical companies.
- Provide leadership and oversight to clients engaged in outsourced manufacturing, toxicology and clinical activities.
- Regulatory and drug development staff assigned to lead activities on behalf of client or as support to internal resource and subject matter experts.
- Numerous projects from 6 months to several years in length.
- Extensive CTA support.
- Support for major CMC changes.
- Regulatory guidance and leadership during submissions.
- Driving products towards, into and through clinical development.

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