DIAMOND
PHARMA SERVICES

REGULATORY ♦ PHARMACOVIGILANCE ♦ COMPLIANCE

CLINICAL TRIAL APPLICATION SERVICE

The CTA team at Diamond Pharma Services is integrated into the Regulatory Development Department. The team has extensive experience in CTA activities for a wide range of product types.

- New chemical entities
- Biologics
- Advanced therapy medicinal products (gene & cell therapy).

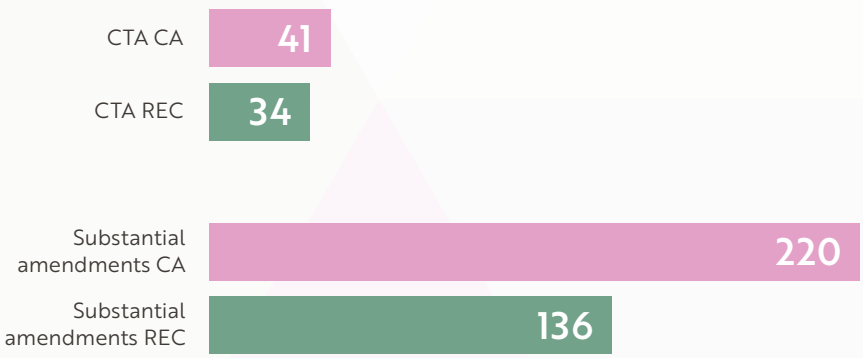
Diamond have expertise advising and supporting:

- CTAs submitted to many EU national competent authorities
- EU wide competent ethics committee requirements
- Voluntary Harmonisation Procedures (VHP)
- Genetically Modified Organism (GMO) applications
- Substantial amendments, end of trial, etc.

The team can offer both outsourced CTA department coverage as well as specialist ad hoc advice to the Regulatory and Clinical teams within Sponsor companies.

Diamond can also provide an EU regulatory team to help non-EU Sponsors to coordinate the interface between the Sponsor's Regulatory/Clinical Teams and their large CROs managing clinical operations. In this model Diamond has demonstrated process improvements for US Sponsors by providing a team of EU specialists to integrate with the Sponsor's internal US specialists.

CTA STATISTICS 2016/2017



OUR CASE STUDIES

Top 10 Global Pharmaceutical Company:

- Responsible for UK & Ireland CTA submissions.
- Competent Regulatory Authority and Ethics Committee submissions.
- Dedicated project leader with access to CTA department staff.
- Ongoing long term programme (2 years+).
- Flexible resource provided from an adaptable team experienced in the working practices of the client.
- Improved workflow delivered to client reducing internal headcount burden.

ATMP Programme:

- Bespoke CTA and technical regulatory support provided.
- Regulatory interface between Sponsor and Multinational CRO.
- Expert EU advice provided.
- Coordinated, GMO applications, CTA, complex response to questions to multiple EU national agencies.
- Trusted group acting as specialised EU regulatory team for both EU and non-EU based sponsors.

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