DIAMOND PHARMA SERVICES

REGULATORY ♦ PHARMACOVIGILANCE ♦ COMPLIANCE

ATMP REGULATORY SUPPORT

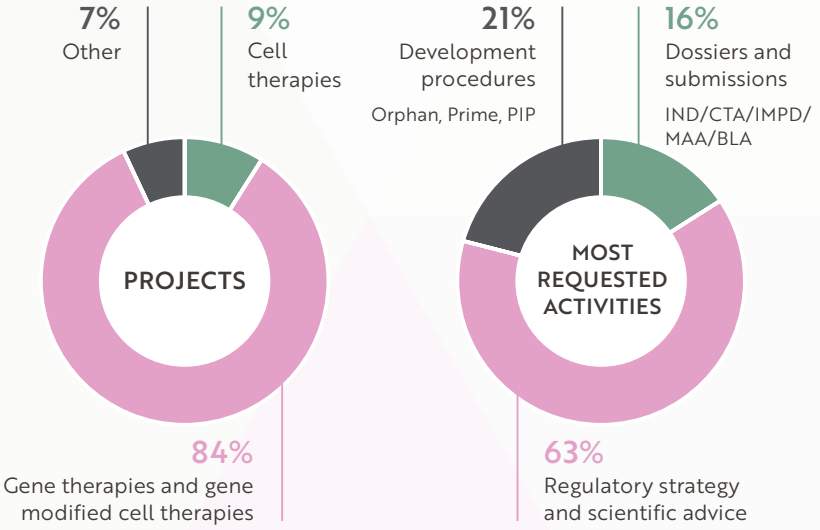
The team at Diamond Pharma Services has world class regulatory experience in assisting companies developing advanced therapy medicinal products (ATMPs). Support can be provided for both cell and gene therapy products for Europe and the US.

Diamond have supported more than 45 different gene and cell therapy development programmes. These programmes contain a diverse set of ATMP technologies including various viruses and vector types, oncolytic viruses and an increasing number of gene modified cell therapy modalities. Notably, Diamond supported the MAAs and development programmes for YESCARTA® and GLYBERA.

Key services offered:

- National and EMA scientific advice meetings
- Regulatory GAP analysis and development plans
- SME status applications
- Prime applications
- Orphan designation applications
- Paediatric investigation plans
- CTA and IND support
- MAA / BLA
- US agent
- FDA meeting support.

ATMP STATISTICS How we have supported others:



OUR CASE STUDIES

US to EU Transition (Cell Therapy):

- Company in clinical development in US and planning to open trial sites in the EU.
- Regulatory gap analysis and development plan provided to define the EU regulatory strategy.
- EU scientific advice taken.
- Successful orphan application.
- IMPD written, liaising with EU manufacturer to provide the detail expected by national agencies in the EU.
- Regulatory support provided throughout the CTA.

Full EU Regulatory Provision (Gene Therapy):

- Company in clinical development in US.
- Regulatory gap analysis and development plan provided to define the EU regulatory strategy, support in scientific advice, Orphan and Prime submissions.
- Carried out the role of EU regulatory support to Sponsor providing full CTA management services for over 20 CTA submissions and GMO application support.
- MAA leadership through to approval.

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