DIAMOND
PHARMA SERVICES

REGULATORY ♦ PHARMACOVIGILANCE ♦ COMPLIANCE

MAA SUPPORT AND LEADERSHIP: US TO EU

At Diamond, we have been successful in supporting US clients to transition their late stage clinical development programmes through to Marketing Authorisation Application (MAA) in the European Union (EU). We deliver bespoke solutions based on a pragmatic and strategically focused approach.

We support clients through clinical development, engaging early to provide an integrated EU strategy within a global development programme. However, commercial reality does not always permit an integrated and global approach from the outset. Some real-world situations necessarily consider EU submissions later in development (including post-NDA/BLA scenarios).

Regardless of the stage of development and maturity of the programme, our team can draw on past experience to provide the operational and strategic support needed to negotiate the path towards MAA.

HOW DIAMOND MAKES A DIFFERENCE

Proactive strategic advice

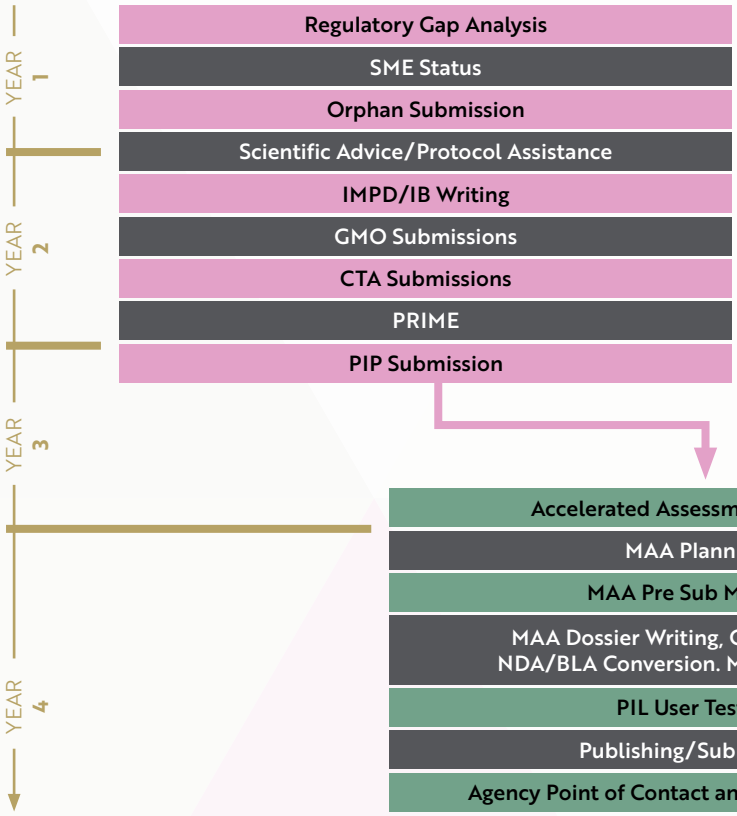
Proactive interactions with regulators and clients

Diligent operational support

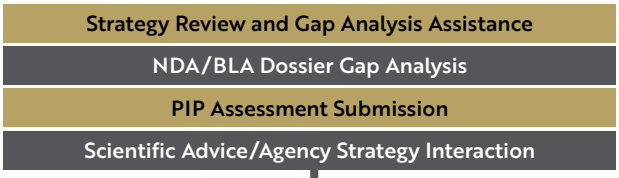
A true desire, alongside our client, to be the first, e.g.:

- Supported the first gene-therapy approval in Europe
- Supported the first CAR T-cell therapy in Europe
- Supported the first treatment for the rare disease, familial chylomicronaemia syndrome, in Europe

INTEGRATED DEVELOPMENT ROUTE TO MAA



NDA/BLA TO MAA CONVERSION



Suite 2, Ground Floor, Field House, Station Approach, Harlow, Essex CM20 2FB **T** +44 (0)203 911 9410 **F** +44 (0)1279 418 964

diamondpharmaservices.com