

Early Clinical Development Physician - Immunology

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Китай

Сводка

Provide medical and scientific expertise and leadership to:

1. Drive successful China implementation of early global program and strategies to achieve clinical Ph1 and Ph2a studies
2. Support China late programs by codeveloping and implementing early development and ESS strategies to meet regulatory requirements
3. Support Translational Research in developing new indications, endpoints and biomarkers, using in vitro, in vivo, or in silico methods
4. Provide scientific expert assessments and support for in-licensing opportunities, including due diligence if needed
5. Leveraging China's life science ecosystem to accelerate scientific innovation.
6. Foster collaboration with internal and external partners
7. Support China RDC development

Note: A TME may do some or all of these or alternate among them, as program needs dictate

About the Role

Major accountabilities:

China Activities

- Represents as China scientific lead in the global project team, driving China strategy for global early clinical development through collaborative partnership with global and local functions
- Fosters China cross-functional collaboration to steer the China development plan, to lead China medical feasibilities, and to ensure timely regulatory, clinical, commercial and external experts' inputs into the China clinical development strategy and plan
- Ensures smooth clinical allocation and execution in China with highest medical standards to accelerate translational from bench to bed. To make sure the study design, execution and biomarker strategy in line with GCP, health authority guidelines, disease endpoints and local medical practice. Timely share such information and local requirements with global study team.
- Represents as the key interface between global study team and China local team, study sites/investigators and CRDs (if applicable) for study related activities
- Represents as one of the key leaders in country feasibilities and site feasibilities
- Works as the key local scientific contact person to answer medical related queries/questions. Works closely with China TR (Translational Research) group to design or participate Nopis studies collaborating with Chinese investigators/sites, in order to identify, develop, and implement strategy for preclinical support of clinical program-related scientific objectives. This includes assessment of medical needs, proposal of clinical development pathways, and review of preclinical data for clinical implications, and other relevant activities. This may include methodology studies to identify and validate novel endpoints for early decision making in PoC studies.
- Works closely with China GDD and NPP team to make China early development strategy, including indication prioritization, disease footprints/mapping, patient journey and competitive landscape.
- Works closely with biomarker experts to make China biomarker strategies
- Participates Due Diligences and non-project related work streams representing the function if needed

Global Activities

1. Early clinical projects (pre-PoC, "Discovery"):

- Develop, in collaboration with TM TA Head or experienced Translational Medicine Expert, and work with teams to carry out, strategies for the Translational Medicine component of drug development projects from Research to clinical PoC in single or multiple indications, including PIE-PoCs.
- Lead global project teams through PoC phase to drive implementation of the PoC strategy
- Convene relevant (internal and external) experts to consider the proposed approach to PoC; present plans for approval at relevant decision boards
- Be responsible for clinical portions of the Integrated Development Plan (IDP, including the CDP and CPP)
- Evaluate clinical centers and foster communication with crucial collaborating investigators, regulatory authorities, and other stakeholders

2. Late-stage clinical projects (post-PoC, "Profiling"):

- If needed, act as a key leader in developing the Ph2-3 and post-approval profiling strategy for drug programs in collaboration with TM TA Head or Translational Medicine Profiling Head, representing TMDP on Global Project Team (GPT) along with other TM line functions. Provide support for dose selection, study design and other clinical pharmacology matters throughout the development cycle. Oversee conduct and interpretation of studies to support the pivotal trials, such as special populations, drug-drug interactions, mechanism of action assessments, Pediatric Investigational Plan, etc.

3. Translational Research (TR; indication seeking, endpoint and biomarker development):

- In collaboration with TM TA Head, BR Research scientists, other TM line functions (BMD, CS&I, PCS, PKS), develop strategies to identify initial or expansion (PIE) PoC indications, and to obtain sufficient evidence to fund these ideas.

Essential Requirements:

- Doctoral degree, MD required in most cases. Demonstrated excellence and clinical expertise in relevant medical subspecialty.
- At least 5 years' experience in clinical research and development in a pharmaceutical/biotech company, CRO, or academic medical center, or related experience. Early development and translational medicine experiences are preferred. MNC experiences is a plus.

- Excellent written and oral communication/presentation skills, ability to influence and make impact
- Independence: Able to work independently as outlined above,
- Innovation: Seeks out new clinical discovery opportunities and PoC approaches.

Disirable Requirements:

- Demonstrated passion for science, self-motivated, be willing to work flexibly, especially when night meetings were not avoided when important cross location project discussions are needed.
- Expert in field with good relationships with external experts
- Strategic mindset and critical thinker, with strong analytical skills

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 Employment Type
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