

Director, Clinical Development Advanced Methods

Job ID

REQ-10037791

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Summary

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives.

To do this, we are optimizing and strengthening our processes and ways of working as well as innovating the way we design our clinical trials. We are investing in new technologies and building specific therapeutic areas and platform depth and capabilities – all to bring our medicines to patients even faster.

We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to.

Apply today and we can thrive together!

This role will be based in London, UK in a hybrid working approach

About the Role

Are you ready to become the Director, Clinical Development Advanced Methods? This is a pivotal role within Clinical Development, whereby the individual will be instrumental in applying advanced methods and innovative designs to accelerate drug development programs, increase trial success and advanced label claims.

The Director Clinical Development Advanced Methods (DCDAM) partners with the Head Clinical Development Advanced Methods to bring advanced clinical capabilities and non-conventional, innovative designs and methodologies to clinical development plans (CDP) and study designs within the Development organization. This includes but is not limited to adaptive clinical trial designs, use of master protocols, applying model informed drug development, strategic use of real-world data, such as data linkage/tokenization, use of hybrid control arms.

The DAM independently collaborates within Clinical Development (CD) as well as with partner functions such as Analytics, Regulatory Affairs, Data & Digital, GMA (e.g. for real world evidence) or Early Development, to deliver on integrating advanced methodologies in clinical development plans and clinical trials, with a focus on accelerating programs, increasing trial success and advancing label claims. The DCDAM may deputize for the Head Clinical Development Advanced Methods as the CD representative or CD lead for enterprise-wide innovation projects, ensuring CD perspectives are represented.

Major accountabilities:

- Participates in the development and maintenance of a protocol design lab (PDL), in partnership with the Head Clinical Development Advanced Methods, to drive advanced trial designs and methodologies to clinical development plans and study designs within the Development organization. Leads development and maintenance of subparts of the PDL. May act as deputy for the Head CD Advanced Methods.
- Leads cross-functional teams to implement selected innovative designs and methodologies within the Development organization applying a nimble and agile approach that allows to leverage existing expertise
- Independently works with key partners within Clinical Development and other functions e.g. Analytics, Regulatory Affairs, Data & Digital, GMA (e.g. for real world evidence) or Early Development
- Partners with Clinical Development Heads, Global Program Clinical Heads and Clinical Development Medical Directors to understand their programs specific plans and needs related to advanced designs and data uses. Provides consultancy in collaboration with functional experts (Analytics, Regulatory Affairs, Real World Evidence, Biomarker, Patient Engagement, etc). Also leverages advanced methods and approaches stemming from the Development Units and support knowledge sharing thereof.
- Independently identifies, drives and supports innovative projects relevant to clinical design and clinical development plans
- Proactively monitors internal and external trends in clinical development and leads cross-functional evaluation of applicability to Novartis.
- Leads or represent Clinical Development in cross functional Novartis initiatives, bringing the CD perspective and needs into the discussion
- Is responsible for capability building for the CD community in selected aspects of advanced methodologies in clinical development
- Engage with key functions (Analytics, RA, GDO, etc) to ensure cross-functional awareness and alignment on advanced clinical methodologies

Key performance indicators:

- Achievement of unit objectives -Delivery of Clinical Trials to quality standards and agreed timelines - Adherence to Novartis policy and guidelines and external regulations.

Your Experience:

- Advanced life science degree (Ph.D, PharmD, Master in Public Health).
- Minimum 12 years of relevant experience in pharmaceutical industry preferably across several disease areas and development phases
- Working knowledge of Drug Development processes, with extensive experience in designing and conducting clinical trials, with a deep understanding of regulatory requirements and guidelines.
- Successful relationship builder and communicator with experience leading cross-functional work streams, driving program excellence and engaging functional partners
- Fluent in English

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting, and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?

<https://www.novartis.com/about/strategy/people-and-culture>

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

Join our Novartis Network:

Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Division
Development
Business Unit
Universal Hierarchy Node
Standort
Vereinigtes Königreich
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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