Clinical Sciences and Innovation
Postgraduate Program
“The CS&I Postgraduate Program at Novartis provides the possibility to gain insight into the pharmaceutical industry, learn about early drug development and experience our diverse and modern work environment at the Novartis Campus in Basel. This program will allow you to learn the technical and communication skills to successfully design and execute early phase clinical trials – skills that are valuable and marketable to all facets of pharmaceutical industry.”

Rachel Morgan
Global Head, Clinical Sciences and Innovation
The Clinical Sciences and Innovation (CS&I) Postgraduate Program is an opportunity to gain experience in the exciting global function of drug discovery in early phase clinical trials.

**Mission of Clinical Sciences and Innovation**

We are a dynamic group of clinical scientists who lead the early phase clinical trials conducted by Novartis, ensuring they run smoothly, on time and with the patient’s interests at center stage. Further we are in charge of first-in-human trials to test safety, tolerability and exposure of a drug and proof-of-concept (PoC) trials that test drug efficacy. These studies form the basis for the company’s decision on whether to develop the drug further (Phase III studies). We also conduct studies to further profile compounds as they move through later phases of development to registration and beyond. This includes clinical methodology and pharmacokinetic studies designed to provide additional scientific and mechanistic understanding and support drug label claims.

**Purpose**

The CS&I Postgraduate Program is offered as a 1 or 2* year program designed to provide highly motivated candidates the unique opportunity to gain practical experience in early clinical drug development.

The goal of the Postgraduate Program is to provide qualified candidates with the training and experience to become highly skilled clinical research scientists and to foster professional growth, enhancing the potential for a successful career in the pharmaceutical industry.

*reviewed each year
Postgraduate Program Overview

The CS&I Postgraduate Program provides practical experience in early clinical drug development in an immersive pharmaceutical research environment. You may be exposed to a number of fundamental early clinical research studies such as first-in-human, proof-of-concept, dose escalation, pharmacokinetic drug-interaction and mechanistic profiling studies during the course of the program. In addition to early phase clinical research, you will also gain insight into the multi-disciplinary aspects of the drug development process.

During the 1 year Postgraduate Program, train to become a Clinical Trial Associate through assistance in delegated tasks to support the clinical trial team in the conduct of clinical trials within Translational Medicine and ensuring that all essential documentation is collected, maintained and filed during the study.

During the 2 year Postgraduate Program, train to become an associate clinical scientist through assistance in delegated tasks to support the clinical trial team in the conduct of clinical studies within Translational Medicine and ensuring that all essential documentation is collected, maintained and filed during the study. With increasing experience, support study leads as co-lead with the potential to become a named study lead in the last part of the program.

Specific responsibilities may include:

• development and review of study protocols, informed consent and case record forms;

• analysis of study data and preparation of final study reports;

• development and management of essential regulatory documents;

• selection and initiation of study centers;

• coordination of all operational aspects of conducting clinical trials, such as tracking of budget and timelines, and liaising with external vendors;

• understanding and maintaining compliance with Good Clinical Practice (GCP) guidelines and regulatory requirements.
You will participate in meetings with experts who will be reviewing the scientific and operational aspects of a clinical trial. You may also have the opportunity to participate in meetings with external expert panels as well as contribute to an Investigational New Drug (IND) application – the process which allows clinical testing to begin in humans. You also may be called upon to contribute to a New Drug Application (NDA) – the regulatory process which is the final step leading to the approval of a new drug.

The scope of work will allow you to work within international teams and to interact with different departments within Translational Medicine and the greater Novartis group, for example Biomarker Development (BMD), Drug Metabolism and Pharmacokinetics (DMPK), Preclinical Safety (PCS), Discovery & Profiling (D&P), Biomedical Statistics, Technical Research and Development (TRD) and Drug Regulatory Affairs (DRA).

“Clinical research is at the core of drug development and is key to provide society with innovative medicines. Through this program, Novartis offers a unique opportunity to gain insights into the different aspects of clinical trials, to develop your skills and to collaborate in an international environment on cutting-edge projects.”

Simon Badoud
CS&I Postgraduate Coordinator
Drug Discovery and Development Process

In drug discovery several methods like high throughput screening and computer-based design are used to find chemical compounds or biologics that bind to an identified target. Of more than 10,000 hits tested in drug discovery only one may eventually lead to a drug that is sold to the public.

There are different phases of clinical trials, each of which is focused on evaluating drug safety and efficacy. In Phase I of clinical trials the drug is usually tested in health volunteers to determine its safety and pharmacokinetics. In Phase II the drug is given to patients to evaluate efficacy and to determine the optimal dose. In addition the safety and side effects are evaluated as these may be different in patients compared to the health volunteers tested in Phase I. In Phase III large numbers of patients are recruited for research with the investigational drug to confirm the efficacy, monitor side effects, and compare it to established treatments and to gather additional information to allow the drug to be used safely.

Finally data from all clinical trials are collected and compiled into the registration documents for approval by the Health Authorities (in each country).
Qualification and Requirements

- Advanced degree (minimum MSc or PhD) in Life Sciences
- Fluency in English (oral and written)
- Good organizational and interpersonal skills, i.e. demonstrates ability to communicate well with people from a variety of backgrounds/cultures and at different hierarchy levels inside and outside the company
- Ability to work independently and manage multiple priorities
- Some knowledge of clinical trial design, execution and operations would be beneficial

Novartis is an equal opportunity employer committed to embracing and leveraging diverse backgrounds.

How to apply

To apply please send your CV and letter of motivation to csi.graduate@novartis.com

Applications for the program should be submitted between March 15 and May 15.

The program starts in August.