<u>Navigating the Regulatory Maze – Early Stage</u> <u>Development Strategies</u>

Researchers across the globe face common barriers in translational research that can delay the development of new interventions for patients in need.

This seminar will focus on describing the strategies and benefits of implementing a stage-gate approach in early non clinical development and for Phase 1 clinical development.

Benefits include:

- Clear go no-go decision points
- Higher probability of success moving from non clinical to clinical phase
- Clear and favourable exit strategies

Presenter: Dr. Niamh Kinsella



With 20 years of experience from biologics development, Dr. Niamh Kinsella provides tangible and actionable advice to optimise early drug development plans.

Agenda

10:00 am	Registration and coffee
10:30 am	Welcome: Dr. Stephanie Krumholz, General Manager NDA Switzerland
10:40 am	Presentation: Navigating the Regulatory Maze – Dr. Niamh Kinsella
11:30 am	Question and answer session
11:50 am	Closing remarks
12:00 pm	End of seminar

13:30 – 17:00 Take the opportunity to book a one to one 30 min meeting to speak directly with our experts.

Email <u>zurich@ndareg.com</u> to book your time now.

Date: 31st October 2019

Time: 10:00 am – 12:00 pm (with the opportunity to book 1-1 meetings afterwards)

Venue: Bio-Technopark, Auditorium, Wagistrasse 25, 8952 Schlieren

The seminar is held in collaboration with <u>Bio-Technopark®Schlieren-Zürich</u> and will be an open and interactive workshop with the opportunity to ask questions. Specific questions can be sent in advance to <u>zurich@ndareg.com</u>

Registration: RSVP by Friday 25th October 2019 to zurich@ndareg.com

Contact: Katharina Gerstl at katharina.gerstl@ndareg.com

If you are unable to attend, please advise us no later than two days before the seminar.

We look forward to seeing you there!