VENTURE BASE CAMP

# Clinical Study Design

**Organized by**

RIFC | BRBC – A BIRAC - Venture Center Initiative | VENTURE CENTER | birac – Ignite Innovate Incubate

# For Medical Devices and In Vitro Diagnostics

**(Thurs - Sat) 8 - 10 August 2019 | Time: 9 am – 6 pm**
**Lecture Theatre @ Venture Center, 100 NCL Innovation Park, Pune.**

## FOCUS

Work on actual documentation and processes required for regulatory approval purposes with CDSCO and ethics committees viz., Clinical Investigation Plan, Clinical Performance Study Plan, Investigator's Brochure (IB), Informed Consent Form and many more.

## WORKSHOP HIGHLIGHTS

- Understand clinical studies requirements for new treatments using devices and diagnostics.
- Understand design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.
- Understand rights, safety and well-being of human subjects, scientific conduct of the clinical investigation and the credibility of the results, responsibilities of the sponsor and principal investigator, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

**Interested participants need to fill in registration form at the following link**
**http://bit.ly/aug19-clinicalstudy**

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**More details available on**
**http://rifc.venturecenter.co.in/events/**

**Technical queries:**
**Navnath Kadam: 020-25865877/76 | navnath@venturecenter.co.in**

**Registration related queries:**
**Lipika Biswas| 020-25865877/76 | eventsdesk@venturecenter.co.in**