



# BECOME A CERTIFIED SUCCESSFUL CLINICAL TRIAL INVESTIGATOR (DOCTOR) AND BE A PART OF THE BOOMING CLINICAL RESEARCH SUCCESS STORY

#### **CLINICAL RESEARCH WORKSHOP IN PATNA**

SUNDAY, 8<sup>th</sup> JUNE 2014 – 9.00 A.M. TO 5.00 P.M.

#### Why consider being a clinical trial investigator?

Clinical trials are defined as any investigation in human subjects intended to discover or verify the clinical, pharmacological and / or pharmacodynamics effects of an investigational product with the object of determining safety and/or efficacy. It is through these trials that investigational drugs, devices, and diagnostics may show their benefits. Clinical trials have several layers of protection for human subjects including, Regulatory bodies (viz. USFDA; DCGI, ICMR); Independent Ethics Committees & Institutional Review Board (IRB), data safety monitoring boards (DSMB) that review the data while a clinical trial is in progress to ensure that subjects are not exposed to undue risk and careful monitoring and attention from the investigator and sponsor. Being involved in clinical research can be a positive experience offering an opportunity to learn, become exposed to new medical therapies and provide additional options or alternative treatments for your patient population. Some of the key benefits of becoming successful Clinical Trial Investigator are:

- Explore New Treatments and/or expense support for Patients
- Publications
- Research Grants
- Opportunity to learn and expand skills
- International exposure
- Be at the cutting edge of medicine.
- Play a critical role in medical product development.
- Help improve the health of patients.
- Increase your professional development and recognition.
- Gain experience and credentials that could lead to grant funding and investigator initiated ventures.

#### Why Compliance & Training for Doctor is Important?

- Compliance assures the collection of reliable data for submissions to regulatory agencies.
- Pharmaceutical Companies and CROs prefer to engage medical practitioners and site staff who are GCP Certified.
- GCP Training & Certification is regulatory requirement.

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• A good GCP training program would equip you with the necessary knowledge to conduct the clinical trials as per GCP Principles and regulations.

#### Topics which would be covered in workshop is:

- Introduction to Clinical Research & ICH GCP Principles
- Ethics in Clinical Research
- Essential Documents in Clinical Research
- Regulatory Affairs
- Roles & Responsibilities of Investigator
- Informed Consent & Subject Recruitment
- Conduct of Clinical Trials
- Adverse Event Reporting
- Quality Assurance in Clinical Trials
- How to contact and write proposals to Pharma company or CROs for Clinical Trials
- How to conduct clinical trials in your own medical setup

**Fee:** Rs. 3,500/- (Inclusive of CRQA ICH GCP Certification, Workshop Folder; Lunch/Tea/Coffee). Fee payable by 'bank draft or cheque' in favour of 'CRQA, unit of THEPL', payable at New Delhi

#### **About Organizers**

CRQA is an independent auditing and regulatory consulting based in Delhi/ NCR, India. We are a firm comprised of auditors specializing in Total Quality Management. Our expertise covers entire spectrum of GCP and GLP quality, audits and inspection preparedness solutions. We have scientific experts to cover quality in clinical trial design to training. We offer our clients a team of highly qualified QA auditors who provide comprehensive training, conduct audits, inspection preparedness. Academic Partner for the program is Cliniminds, internationally accredited Clinical Research education organization.

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## **Registration Form**

### **Registration details:**

**Nomination Details** 

- The workshop fee is INR 3,500 per person inclusive of all taxes.
- The above cost includes workshop study material, morning and evening tea and snacks, lunch.
- Registration fee is non-refundable and non-adjustable with other CRQA programs.

| Name:                                  |                      |              |
|--|----------------------|--------------|
| Address:                               |                      |              |
| Designation:                           |                      |              |
| Telephone:                             | Mobile:              |              |
| Name & Address of organization:        |                      |              |
| Extract name & title you would like    | • •                  |              |
| Enclosed is the DD/Cheque No           | for INR              | in favour of |
| "CRQA, Unit of THEPL" payable at N     |                      |              |
| (You can also pay by Credit / Debit Ca | ard / Bank Transfer) |              |
| Date:                                  |                      |              |
| Place:                                 | Signature:           |              |

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