# CLINART–Newsletter

Issue 2, May 2010

## IN THIS ISSUE





Courtesy: Institute of Clinical Research

## EDITOR'S MESSAGE

Adhiti Soni

We would like to open the second issue by thanking all the readers for their kind reviews on the 1st issue of the newsletter. The aim of ClinArt Newsletter will be to keep its readers widely interested in basic and applied clinical research, and to promote interaction and collaboration among researchers from different fields.

In this issue, we will start with an article by Dr.Maha Al Farhan, CEO ClinArt followed by company news. Next we will shed light on the developing clinical research in Saudi Arabia. We would also like to share with you the journey of Mansoor who dreamed of becoming a CRA rather than a retail pharmacist. In addition, the quality of Data Management at ClinArt will be addressed. A glimpse at the recent and upcoming events by ClinArt International. And, finally the training agenda will wrap up this issue. Any reviews about this issue, please keep them coming in

## MENA MACHINE


Dr. Maha Al Farhan, CEO ClinArt International L.L.C, International Clinical Trials May 2010 Edition, Pg 38-42, http://subscriber.pagesuite-professional.co.uk/subscribe.aspx?source=4&eid=6a7cd6e2-2adb-414e-ac85-c4b1c17ff23a

Although clinical trials have been conducted in the MENA region, since the 1990's recently there has been a rapid development in the infrastructure of clinical trials. There are frequent requests by pharmaceutical companies to conduct clinical trials in the region. We conducted a survey across the region to obtain precise and accurate up-to-date information about active clinical research ethics committee (REC), and regulatory authorities (RA), the most sought after therapeutic area and recommended investigators. Our survey has established a road map for conducting clinical trials in the MENA region. We do recommend you to update this information twice yearly as

# CLINART–Newsletter

Issue 2, May 2010


laws and regulations are being clarified continuously. It is very important for those planning their studies to have a full understanding of specific capabilities and challenges before considering this region.

## CLINART NEWS

### ABOUT US

ClinArt International is an innovative full service, Clinical Research Organization, complementing pharmaceutical, biotechnology, and medical device companies in their endeavor to introduce emerging products to the market. ClinArt International headquartered in Dubai, is serving the Middle East and North Africa with offices in 3 countries, UAE, KSA and Egypt, giving access to a population of more than 250 million largely unexposed to clinical trials.

### TRANSLATION SERVICES

Medical Translation is a new service started by ClinArt International.

All medical documents such as protocol, informed consent forms, questionnaires, medical reports, handouts, insert leaflets, usage instructions, brochures, flyers, patient diaries and medical packaging material can be translated at ClinArt

In ClinArt we provide,

-Accurately reviewed and revised medical translations

-Fully manual translations, based on well recognized and authorized references and dictionaries.

Our translators have pharmaceutical background and have well established track records in medical translations. Proper Arabic language is used that meets the satisfaction of the end users whether they are laypersons or healthcare professionals.

If required by the clients, ClinArt will deal with different legally authorized translators to legalize our translated documents. The translated documents are validated by randomly choosing subjects from the sector where the original documents are addressed to.

### ORACLE CLINICAL

Oracle Clinical provides the life science industry with an integrated Clinical Data Management (CDM) and Remote Data Capture (RDC) application. Because Oracle understands every aspect of clinical data management in a changing market, ClinArt has come in collaboration with Oracle Clinical. Oracle Clinical can help organizations create solutions for their specific data management and business challenges. Its combination of broad coverage and deep functionality offers unmatched benefits in all aspects of clinical data management

### WWW.CLINART.NET

Check this company's official website for recent events, services provided by ClinArt, and the news; it will all be posted on the website in a timely manner. Articles, brochures as well as the newsletter will also be on the site.

## REGULATORY COLUMN

**Author: Dr. Ranya Shahrouri**

### "SAUDI WATCH "

Clinical research settings in the Kingdom of Saudi Arabia were controlled mainly by the National Bioethics Committee and two major hospitals acting as cornerstones in Saudi research. The national bioethics committee is a central approving committee for other local committees. Major bioethics debates, such as stem cell research, genetic research and the Islamic opinion of different types of research are taking place at the National Bioethics Committee. While the other two hospitals; King Faisal Specialist hospital and research center (KFSHRC) and National Guard hospital (NGH) are conducting major, national, multicenter, clinical trials in the Kingdom.

Recently the Saudi FDA has become active in reviewing all

CLINART–Newsletter
Issue 2, May 2010

clinical trials conducted in the Kingdom. This will allow all investigators to follow the guidelines when they plan to perform a clinical research. Moreover, not only clinical trials will be regulated, but food and drug will also be regulated. After setting regulatory guidelines, the Saudi FDA role is expected to expand using different mechanisms of implementation, to control all aspects of drug and food safety in the Kingdom. According to the Saudi FDA, their role will be in two phases: "The first one will last for a period of five years with effect from the date of the resolution of its establishment and considered preparative and inceptive for phase two" whereas "the second phase will be composed of monitoring, testing and supervising drug and food matters". Their vision is to "be the leading regional regulatory authority for food, drugs and medical devices with professional and excellent services that contributes to the protection and advancement of the health in Saudi Arabia." (From www.sfda.gov.sa ) Kingdom of Saudi Arabia will continue to be the centre for clinical research, the largest among all surrounding countries in terms of the number of researches, but now it will be well-managed with the food and drug administration.

# JOURNEY TO REMEMBER

**Mohammed Mansoor**

Mohammed Mansoor is a newly recruited CRA in ClinArt. He resides in Dubai, United Arab Emirates.

The whole idea of being into clinical trials just landed out of the blue and I am very grateful to be a part of it. It so happened that I was looking for an alternative in the field of pharmacy to being a pharmacist working in the counter; to explore new ways to work and contribute in the field of medicine. Like many people around, I was unaware of clinical trials. So I asked a friend of mine to guide me in various areas in the field of pharmacy. He suggested I join his company Manipal AcuNova, in India. Although I was completely clueless about it, he encouraged me to meet the Director of clinical trials in the same company. I joined as a trainee, knowing not much about it. Everything was just new to me. The people working there were very cooperative and friendly and treated me like one amongst them. I was designated as a trainee with a Clinical research Coordinator (CRC) in AcuNova. There were other departments like Bioavailability/Bioequivalence, Analytical laboratory and clinical laboratory**.** I spent a few months there, learning new things. It was wonderful experience learning about trials, corresponding with various people around exchanging views and ideas.

Later I decided to look further into clinical trials as my career and aspired to be a Clinical research associate. My father had a few good friends in the Middle East who were doctors and they guided me into the field in the Middle East.

A couple of months later, I forwarded my resume through a newspaper daily article to ClinArt, I was short listed for the interview and designated for the post of clinical research associate. A dream came true, took a while but it was great journey from India landing in Dubai to work for ClinArt.

It's been a couple of weeks but I can just say I am really having good experience working under wonderful people around me. In a short span of time, I have a good experience meeting experts in the field of clinical trials. I had the privilege of attending 3 day workshop for Advanced ICH/GCP training organized by ClinArt. It was about ethics dealing with issues of Clinical

# CLINART–Newsletter

Issue 2, May 2010


trials. The training was done by our CEO Dr. Maha Al Farhan, project manager Dr. Shada Sayegh and a special guest Dr. Deven Parmar Vice President - Clinical Research for Wockhardt from Mumbai, India who trained us for 2 days. There were other medical experts too attending the training. It was a bonus pack for a new CRA to meet professionals learning their thoughts and ideas of making great clinical trials**.**

The training was so rewarding, going through most of the areas of Good Clinical Practice. Besides that I met my colleagues from Saudi, Egypt and Qatar. Nice way to start a career.

Not only being knowledgeable in my field is important but also being a good person are most important in my field because it's all about improving human's life that we in ClinArt and clinical trials look forward to. Hoping for a good and prosperous career, I sign off quoting from

BERTRAND RUSSELL: The good life is inspired by love and guided by knowledge.

## QUALTIY MATTERS

**Dr. Maria Antoun**

ClinArt Data management department is always focused on quality. Our main task is to revise the data collected and ensure its completeness and accuracy. To fulfill these criteria and reach superior quality different ways are used.

Our data entry team has medical/ pharmaceutical backgrounds, and this makes them familiar with the medications and therapeutics helping them to work faster on the data.

Every person who can have access to the data base has their own user name and password which acts as an electronic signature.

Two different people will enter the same data, and then the system compares the entries to discover the miniature differences like caps lock and punctuation marks and triggers an alarm. Following which the data is revised for incomplete or irrational input.

Highly qualified medical data managers evaluate the data from the medical and logical points of view. In case of any missing or illogical data, the data management team sends a query to the investigator to verify and confirm the data to guarantee the best quality. Regular quality control and monitoring of the database is performed to evaluate the work of the team and look at their progress.

Serious adverse event alerts are triggered when a SAE is detected or a SAE form is received. Our IT programming allows a notification alert to be automatically emailed to the concerned medical/safety manager at the sponsoring institute or company.

## UPCOMING/RECENT EVENTS

**25th May 2010**: *'Current Status of Clinical Trials across the MENA Region'* will be talked by Dr. Maha Al Farhan, CEO of ClinArt International, Dubai at Pharmaceutical Manufacturing and Biotechnology Middle East (PABME) held at Dubai International Convention and Exhibition Centre, UAE.

**10th 11th May 2010**: '*Working within regulatory frameworks and accommodating FDA Audit*' will be talked by Dr. Maha Al Farhan, CEO, ClinArt International, at 'Cardiovascular Clinical Trials

in Emerging Countries 2010' (CVCTEC 2010) - Clinical Trials Conference which will be held in Prague, Czech Republic.

It will focus on the current problems, solutions and results of conducting cardiovascular clinical trials in key emerging markets, Latin America, Middle East, Central and Eastern Europe, and Asia Pacific.

**26th April 5th May 2010**: *Oracle Clinical /Remote Data Capture Training* for 10 days will be held at ClinArt premises, Dubai Healthcare city.

It will provide a detailed understanding of Oracle Clinical, Thesaurus Management System, and Remote Data Capture and is a workshop for Clinical Research Professionals.

**11th 12th April 2010**: *ClinArt Clinical SOP's and Introduction to Biostatistics Presentations* were held at ClinArt International, Dubai Healthcare city, Block 72, U.A.E.

**8th 10th April 2010**: *Advanced ICH GCP Training* was conducted at Flora Grand Hotel, Dubai, and U.A.E.

Dr. Deven Parmar; Vice President-Clinical Research of Wockhardt Ltd. India was the chief presenter at the training. He offered enormous amount of information on clinical trials.

# 2010 TRAINING AGENDA

Below are the trainings offered by ClinArt:-

**8TH April**, Dubai
Three Days Advanced ICH-GCP

**26th April,** Dubai
Oracle Clinical

**26th April**, Saudi Arabia
Two Days ICH-GCP Phase II Perspectives

**September**, Dubai
Project Management for Clinical Trial

**October**, Dubai
Basic Biostatistics / Two days

**January December**, Dubai
Biostatistics / Complementary

**October**, Dubai
Research Ethics Committee

**December**, Dubai
Research Ethics Committee

All the training services will be provided upon request. For more information please contact Ranya Shahrouri, Training Manager at Ranya.shahrouri@clinart.net, +971 55 4144 227


Courtesy: Institute of Clinical Research