



EUROPEAN CENTRE FOR  
CLINICAL RESEARCH TRAINING

# ECCRT Newsletter



# Welcome letter:

WILLKOMMEN  
欢迎 स्वागत  
BIENVENIDA  
WELCOME  
BIENVENUE ようこそ  
добро пожаловать  
ترحيب BEM-VINDO

Dear Reader,

On behalf of the ECCRT team I would like to personally welcome you to our first Newsletter as a new resource on our website, within everyone's reach.

This resource will not only allow you to get feedback and updates on our activities, but also on any news related to clinical research, interviews, background articles and much more. All this in the spirit of accomplishing our mission:

**“To facilitate Clinical Research professionals to excel in their job for the benefit of patients.”**

It is with great pleasure that we introduce this Newsletter as a means to increase the voice of ECCRT trainers and trainees. This will give you the floor to make your voice heard, to build a space for knowledge and expertise exchange and to improve our services that we provide to all of you. We therefore welcome any ideas that you may have to achieve this.

I want to thank all those that contributed to the creation, design and content of this Newsletter and the next editions to come.

Wishing you a lot of inspiration with this new initiative.



Prof. Dr. **Benedikt Van Nieuwenhove**  
Managing Director ECCRT



# ECCRT Info

Welcome to our first ever newsletter. We would like to use this Newsletter as a new free resource on our website that will keep you informed of the latest news and activities from ECCRT on topics related to Clinical Research and Trials.

By this channel we can reach out to our customers in an organised, creative and interactive way to better communicate with you. It will also allow you to share with us your articles, opinions, reviews, testimonials, life experience and topics related to Clinical Trials, Clinical Research, Medical Devices and Pharma so that your voice is heard. This will help accomplish our mission to train talent and facilitate Clinical Research professionals to excel in their jobs for the benefit of patients and to contribute to the well-being and health of the general population.

This Newsletter will be published periodically. Through here we can advertise your non-profit organisation, company, industry, share and/or publish your articles, stories and events. Just send an email to: [info@eccrt.com](mailto:info@eccrt.com)

## A glimpse of ECCRT:



eLearning Courses



Expert Trainers



Training Locations



Years of experience



**+12 000**  
People Trained



**+90**  
Open Courses

# What is ECCRT?

ECCRT is a **professional clinical research training** provider focusing on the transfer of implementable knowledge for the day-to-day activities of our participants, whether being new to the industry, starters on the job, or seasoned professionals. Founded in 2000, we have provided training and coaching to over **12,000** people.

Our mission is to facilitate Clinical Research professionals to **excel** in their job for the benefit of patients. We aim to achieve this by providing clinical research professionals with competencies to develop new therapies for patients **quicker** & more **efficiently**, without jeopardizing quality or **safety**.

The ECCRT approach reflects Benjamin Franklin's statement: *"Tell me and I forget. Teach me and I remember. Involve me and I learn."*

## Our training methodologies are:

### 01 Classroom

The majority of our trainings are classroom-based, face-to-face, human-centred approach appealing to the importance of the interaction between the students and the trainers.

### 02 eLearning

The Virtual Campus is a unique platform developed for the Clinical Research environment. Through this we provide you eLearning courses and webinars to allow you to learn at your own pace. It offers the possibility to download your certificates, chat with your trainer and share your experience.

### 03 Blended

This learning method combines both Classroom and eLearning methodology that can optimise your learning experience.

Find out more in: <http://www.eccrt.com/open-courses>

### 04 STAR Programmes

STAR Programmes combine a number of training sessions that are key to the development of your career in a specific function or area. It offers a cost-effective and complete approach

for all your needs for the aspired function. It is flexible to your needs, costs 15% lower compared to the individual courses fee, and covers about 80 to 90% of the competencies needed in the Clinical Research domain.

For more information: <http://www.eccrt.com/smart-solutions/star-programmes>

### 05 Tailored solutions

We provide tailored trainings, specific to the needs of the client, consulting and coaching to companies. We will help you with the development and implementation of a project within your team and/or company.

Check it out: <http://www.eccrt.com/tailored-solutions>

### 06 Competency Framework

Together with you, we will make an analysis of the 10 competency domains in Clinical Research required within your team and find which trainings are needed to fulfil these domains.

More details can be found: <http://www.eccrt.com/smart-solutions/competency-framework>

# Announcements



We want you to be aware of our latest activities and news within ECCRT and through this announcements section we can make that happen. You can also connect with us through our **social media channels** in a more day-to-day interactive way.

We want to inform you that:

- The **PM Star Programme** will take place the **11 March to 15 March of 2019** - for more details: <http://www.ec crt.com/courses/pm-star-programme>
- The **new Quality Assurance courses** will take place the first week of **April, the 01 to 05 of 2019** - for more details, check our upcoming courses:
  - ▶ [Writing Audit Reports](#) - 01 April 2019
  - ▶ [Introductory Course on Auditing Investigator Sites](#) - 02 April 2019
  - ▶ [Introduction to System Audits for Clinical Auditors](#) - 02 April 2019
  - ▶ [A risk-based approach to Clinical Audits](#) - 03 April 2019
  - ▶ [Auditing Clinical Development Documents](#) - 04 April 2019
  - ▶ [Communication and Appreciative Auditing](#) - 04 April 2019
  - ▶ [Clinical Service Provider Audits](#) - 04 April 2019
  - ▶ [Audit and Inspection Readiness - How to be prepared!](#) - 05 April 2019

## Collaboration with COMBACTE

Combacte battles antimicrobial resistance by speeding up the development of new antibiotics. They developed 4 main projects. For more information [click here](#).

Through this collaboration ECCRT will provide a free online training for Combacte members on **Good Clinical Practice (GCP)**, in order to develop, maintain and train a European network capable and GCP-compliant in clinical investigation sites and clinical trials in the field of infectious diseases and antimicrobial resistance.

Read more in: <https://www.combacte.com/news/online-gcp-training-combacte-collaborates-ec crt/>





## Launch on Facebook

ECCRT is now on Facebook: [@ECCRTTraining](https://www.facebook.com/ECCRTTraining/). The reasons for creating a page on Facebook are multiple:

- ▶ **Build a Community:** Facebook is an excellent tool and place to gather our public, to interact with you, to provide content and keep you informed of the latest activities, to share opinions and to offer feedback. This social media platform has more than 2.2 billion global monthly active users in 2018.
- ▶ **Increase our reach:** Did you know that Clinical Research is one of the most regulated industries in the world, perhaps even more than the nuclear industry? Our goal is clear, and to accomplish it we need to make sure everyone in the Pharma Industry, Clinical Research, CROs etc., are aware of what we do and offer in order to excel in their job for the benefit of the patient.

We hope to publish more personal and general content, including our promotions and deals we will periodically offer.

Check out our page: <https://www.facebook.com/ECCRTTraining/>



## ECCRT's Voice Corner

ECCRT is proud to announce the creation of **ECCRT's Voice Corner**. This is created with the intent of making your voice heard by us and by the Clinical Research environment and to create a community within this range of topics and matters. We do believe that interaction amongst colleagues is an effective approach in the learning and teaching pathway.

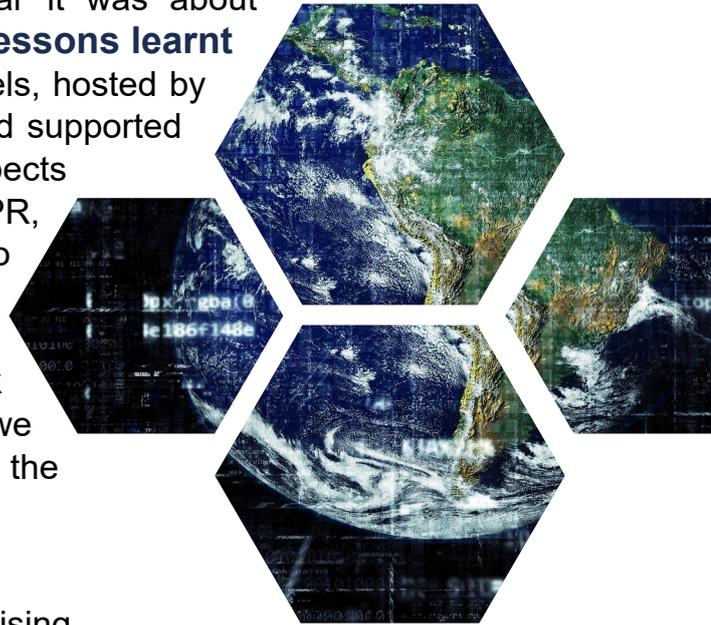
**“Teaching is listening, learning is talking.”** - Deborah Meier.

We want to gather your testimonials, life experiences, interviews with trainers and trainees to share within our community. We hope you can contribute for a more inclusive interaction by providing your view to: [info@eccrt.com](mailto:info@eccrt.com)





We organise a Conference each year- this year it was about **Demystifying Clinical Data Transparency – lessons learnt so far**. This 2 day Conference was held in Brussels, hosted by 15 experts from the field, sponsored by EFPIA and supported by EFGCP. It covered topics from regulatory aspects such as EMA policy 0070, the impact of GDPR, and the use of big data in modern medicine, to anonymisation and included workshops and interactive presentations on the pros and cons of data transparency in clinical trials. The feedback we got from the attendees was very positive and we would like to thank all of you who contributed to the development and the high-quality content.



**#ECCRTConference2019**

We hope to see you at our next event we are organising in September 2019 and at the beginning of next year.



**JOIN ECCRT**

Join our team - work for ECCRT as a **Training Assistant:**

Apply - or for further information: [HR@eccrt.com](mailto:HR@eccrt.com)

**Job description:**

- ❖ Administrative support for ECCRT services
- ❖ Day to day communication with trainers and participants
- ❖ Maintain databases and trackers
- ❖ Coordinate logistics with training/event venues
- ❖ Organise course materials and feedback surveys
- ❖ Agenda Management; Assist with course schedule
- ❖ Reply to enquiries from customers
- ❖ Daily Maintenance of the ECCRT Virtual Campus and website: routine user management, content maintenance
- ❖ Collect and summarize data for QA meeting

**Profile:**

- ❖ Secretarial degree or relevant experience in administrative functions
- ❖ Good verbal and written communication skills (English, Dutch and French)
- ❖ Work independently to a high standard and take initiatives where needed
- ❖ Solution focus
- ❖ Good IT knowledge and skills (MS PowerPoint, Agenda & E-mail management, etc.)
- ❖ Capacity to plan, set priorities and manage time
- ❖ Personal qualities: motivation, reliability, team spirit
- ❖ Be efficiency driven; looking for continuous improvement for all administrative matters

2019

Dates might change - check our website for the latest updates

## March

## Course Schedule

- |                                                                             |                                                                                              |
|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| 11: <a href="#">Clinical Project Management</a>                             | 18: <a href="#">The Belgian Clinical Trials Law of 2017: A Clear View on Rules (webinar)</a> |
| 13: <a href="#">People Management</a>                                       | 19: <a href="#">Microsoft Project Basics for Clinical PM</a>                                 |
| 14: <a href="#">Risk Management in Clinical Research (Blended Learning)</a> | 25: <a href="#">Foundational ICH-Good Clinical Practice</a>                                  |
| 14: <a href="#">Train the Trainer</a>                                       | 26: <a href="#">Clinical Research Training for Junior CRAs</a>                               |
| 15: <a href="#">Legal Basics for Clinical Study Contracts</a>               | 28: <a href="#">Introduction to Oncology for CRs</a>                                         |

## April

- |                                                                         |                                                                                       |
|-------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| 01: <a href="#">Writing Audit Reports</a>                               | 04: <a href="#">Communication and Appreciative Auditing</a>                           |
| 02: <a href="#">Introductory Course on Auditing Investigator Sites</a>  | 04: <a href="#">Clinical Service Provider Audits</a>                                  |
| 02: <a href="#">Introduction to System Audits for Clinical Auditors</a> | 05: <a href="#">Introduction to Inspection Readiness</a>                              |
| 03: <a href="#">Risk Based Approach to Clinical Audits</a>              | 08: <a href="#">The European Clinical Trial Regulation 536/2014 - A Clear Outline</a> |
| 04: <a href="#">Auditing Clinical Development Documents</a>             | 10: <a href="#">Clinical Research Training for Junior CRAs</a>                        |

## May

- |                                                                            |                                                                                    |
|----------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| 06: <a href="#">Introduction to Clinical Research with Medical Devices</a> | 09: <a href="#">Medical Device Regulations</a>                                     |
| 06: <a href="#">Advanced Clinical Project Management</a>                   | 13: <a href="#">Foundational ICH-Good Clinical Practice (GCP) E6 (R2) Training</a> |
| 07: <a href="#">ISO14155 Training (E38)</a>                                | 14: <a href="#">Clinical Research Training for Junior CRAs</a>                     |
| 08: <a href="#">Leading in a Solution Focused Way</a>                      | 21: <a href="#">Clinical Research Training for Clinical Trial Assistants</a>       |
| 08: <a href="#">Running Medical Device Trials</a>                          | 27: <a href="#">The Belgian Clinical Trials Law of 2017: A Clear View on Rules</a> |
| 09: <a href="#">CRO Management</a>                                         |                                                                                    |
| 09: <a href="#">Influencing Skills</a>                                     |                                                                                    |



## Top Courses:



### **Introduction to Oncology for Clinical Researchers**

Do you want to shift your career toward clinical research in oncology? During this 2-day face-to-face course in which lectures are alternated with interactive sessions with the students, you receive instruction on cancer biology, clinical oncology, and clinical research issues that are particular to oncology. These include the genetic and epigenetic basis of cancer, the classification and staging of tumours, the diagnosis, treatment and follow-up of patients, and the most important instruments used in oncology clinical trials, such as methods of response evaluation, toxicity assessment, and survival end points.

<http://www.eccrt.com/courses/introduction-oncology-clinical-researchers>

### **Clinical Project Management**

What are the skills to become a successful Clinical Project Manager? During these 2-days, you will learn the basics of project management adapted to clinical trials. You will see how to manage clinical trials, setting milestones, doing risk management, allocating staff and budgets, dealing with clients and contracts.

<http://www.eccrt.com/courses/clinical-project-management>

### **Risk Based Monitoring (Blended Learning)**

Have you already implemented Risk Based Monitoring in your organisation? This blended course, which means Classroom + eLearning, introduces the ins and outs of risk-based monitoring in clinical trials. It will give you the rationale for implementing this new approach and how to set it up within your organisation. Through an interactive approach, it will provide you with the basics for risk-based monitoring processes applied to clinical trials.

<http://www.eccrt.com/courses/risk-based-monitoring-0>

### **Paediatric Clinical Development**

Want to have a clear and better overview on the practical and ethical aspects of performing clinical trials with children? If you want to know more about the ins and outs of Paediatric Investigation Plans (PIP) and how to write them; this course is a must! We have revised the programme to now also include a 'sharing best practice session', with input from a seasoned pharma industry expert.

<http://www.eccrt.com/courses/paediatric-clinical-development>

### **Clinical Development of a Vaccine**

You want to understand the activities and specific requirements for the clinical development of a vaccine? This 2-day course highlights the highly demanding activities and specific requirements of regulatory characteristics – the quality, safety, efficacy and also clinical trial performance in the development of vaccines.

<http://www.eccrt.com/courses/clinical-development-vaccine>

# Voice's Corner



## Testimonials



### **Jozef Tanczos**

Course: **ISO 14155**

Company: **MIRACOR MEDICAL**



I am thankful for Marleen and Benedikt that have provided a very enriching experience not only for me but to all participants, through an interactive course and case based training, striving people to participate rather than just listening, and through the participation of an audience with mixed level of experience. The feedback I received from them was positive, considering the experience they have in the field and business. They confirmed the training session provided implementable knowledge for their day-to-day work, especially through the case-based workshops.

### **Milcah Kahkelam Bungwa**

Course: **FOUNDATIONAL ICH-GOOD CLINICAL PRACTICE (GCP) E6 (R2) TRAINING**

I now have a better understanding of the GCP guidelines, why it is needed and how it should be applied. The course was very interactive giving room for new ideas and hence a better learning opportunity.

## Ioana Andreea Florea

Course: **CLINICAL RESEARCH TRAINING FOR JUNIOR CRAS**

Company: **ABBVIE**

I've managed to acquire new information on the full process, from beginning to end of a complete list of tasks a CRA has to fulfil. - The workshops have helped the info sink in. Meeting new people. Finding out how the clinical research world works in other countries - It is very well structured, delivered and useful.

## Katina Kardamanidis

Course: **CLINICAL PROJECT MANAGEMENT**

Company: **UMC UTRECHT**

Because there was a lot of information covered in two days, I learned a lot, and we were given many tools/templates that we can adapt for our own practice. Workshops on time and budget planning. Quite challenging, but the first time I was actually helped by explanations, step by step on how to do this/ And then I had to DO IT!

## Kristy Fickinger

Course: **CLINICAL PROJECT MANAGEMENT**

Company: **BRAINLAB**

I learnt about:

- ▶ the clinical trial cycle, abbreviations related to pharmaceuticals (given I come from medical device industry this was new), and budgeting / timesheets / forecasting - Same agenda / timeframe of closeout meeting.
- ▶ Strategies for moderating effective Lessons Learned meetings. Unanticipated trial closure procedure (e.g. study stopped for unethical reasons, unblinding procedure, extent to which CPM is involved).
- ▶ Division of tasks that CPM should NOT do

Small group size - Interactive style.

Finally, all the questions were answered and the Trainer constantly clarified understanding of abbreviations, so you never felt silly to ask.



## Interview:



### Why did you enter the field of Clinical Trial?



top of the research.

I am a real scientist but did not want to do fundamental research any more so I thought that Clinical Research was a good alternative. I never regret it since you are always on the

### Why is Clinical Research so important in the modern world?

It was always important, and it is still since it is the only way to have new medicine or medical device on the market. For some diseases, it is the only way to have medicine available to patients.

### What are some fields you think Clinical Researchers and Clinical Trials need to improve?

First, a larger public should be informed about what is CR and the benefit of it. Not only the bad news of it. So the communication around it should be improved. Besides that we need to use better the new technologies to collect data.

### How can ECCRT help to improve those fields?

By training people on CR with, for example, the introduction to CR eLearnings, but also to make people more aware about CR via our social media.

### What do you like the most in ECCRT?

The expertise of the trainers.

### Any experience you want to share?

I am always happy to receive nice feedback from trainees, it is really rewarding.

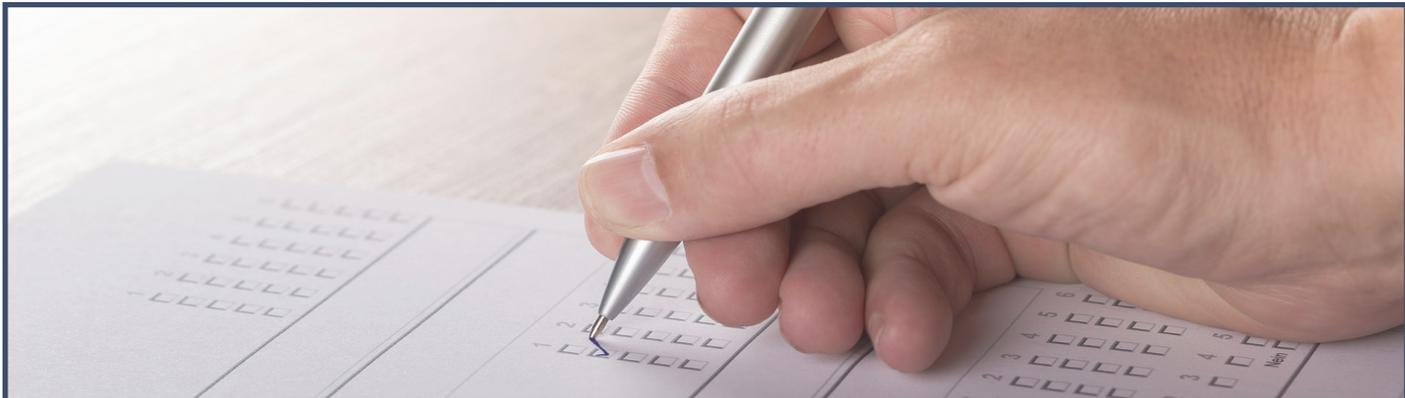
### Ms. Nelle Stocquart is a trainer at ECCRT

Nelle obtained a master in Chemistry in 1997 at ULB. She then worked in variety of companies and institutions as researcher until 2002.

Her first experience in clinical trials was in 2003 when she became an IVRS project manager at S-Clinica, a Belgian CRO. Her wish was finally to be on the field and she became CRA at PAREXEL where she got involved in many international phases II & III from early study stage till closure. She then evolved as project manager in pharmaceutical companies and CRO where she managed local and international studies from phase I to phase IV.

Learn more in:

<http://www.eccrt.com/about-eccrt/trainers?title=Stocquart>



### Your Voice Matters:

We are planning a new 1-day course programme entitled “**Building a Successful Clinical Development Plan**” and would like to understand where the exact needs are in this area.

Developing a medicinal product, biological or device has become more complex and costlier than ever, and a well-thought-out Clinical Development Plan (CDP) can ensure up-front consistency across all phases of the clinical development program, leading to a greater chance of success, whilst minimizing poor decision-making. However, building a concise, well-written CDP that includes the entire strategy for the clinical research and outlining all of the clinical trials is an extremely difficult endeavour that requires input from diverse internal and external stakeholders. By attending this course you will understand the purpose of the CDP, how it connects with other strategic documents used in drug or device development and anticipate what decisions are to be made at each phase of development. You will learn how to develop the CDP so that it supports your company’s product development from a regulatory perspective and according to a Target Product Profile (TPP). Most importantly, you will learn how to build-in milestones and decisions points for accurate and efficient go/no-go development decisions.

**Read more** about the [course description here](#).

Participate in our survey so we can better understand where we need to focus in developing programmes that are suited to your needs and to bring forth more effectiveness to the Clinical Research world.

As a sign of appreciation and if you fill in your coordinates in the survey, we will grant you a **10% discount** when we organise the course.

Fill the survey here: <https://www.surveymonkey.com/r/F8KJSHC>



# Newsfeed

## #ECCRTfact:

According to the Latest [EMA report of the Good Clinical Practice Inspectors Working Group](#)

Did you know?

40%

of the critical findings are related to essential documents



The **Brexit discussions** have been continuing to be in the spotlight of international news. A referendum was held on Thursday, 23 June of 2016 that resulted in a manifestation of the willingness of the British population to leave the EU. After the referendum results, on the 29 March 2017, the UK (under the governance of Theresa May) triggered article 50 of the Lisbon Treaty, which gave the two parties a two-year negotiation to complete this separation process. On 29 March 2019, the UK is scheduled to leave the EU, with or without an agreement, with a possibility to extend the negotiation process for another year.

In the case of a “no-deal” Brexit, the UK would sever all ties with the EU and the UK would no longer be a part of the EU medicines and devices regulatory network and pharma companies would no longer be able to submit data relevant to the UK via the previous Common European Submission Portal (CESP) or other EU portals. To help manage this uncertainty, the UK’s **Medicines and Healthcare products Regulatory Agency (MHRA)** has recently posted guidelines describing the steps to follow for regulatory submissions if Britain leaves the EU without reaching an agreement, including how pharma companies can continue to submit regulatory notification to the UK post-Brexit and even how to change the ownership from one marketing authorisation (MA) holder to another, if necessary.

We recommend for you to read the following information to help prepare for this event:

- Link to Webinars relating to MHRA submissions if the UK leaves the EU with no deal:  
<https://www.gov.uk/government/publications/how-to-make-regulatory-medicines-submissions-to-the-mhra-if-the-uk-leaves-the-eu-with-no-deal>
- MHRA updates on marketing authorisation guidelines post-Brexit:  
<https://www.gov.uk/guidance/medicines-marketing-authorisation-transfer-ownership#history>
- MHRA link to help your business prepare for the UK leaving the EU:  
<https://www.gov.uk/business-uk-leaving-eu>
- “Brexit Impact Scan”: Allows companies in Belgium to calculate the impact of Brexit  
<https://economie.fgov.be/fr/brexit>
- European Medicines Agency (EMA): Provides a guidance to help Pharma Companies responsible for human and veterinary medicines prepare for the UK’s withdrawal from the EU:  
<https://www.ema.europa.eu/en/about-us/uks-withdrawal-eu/brexit-related-guidance-companies>

We will see what will happen the **29th of March 2019**.

*Written by:*



Paula Hemdal



Andre Fernandes



## Article

# How is Clinical Project Management changing with new technologies?



Clinical Project Managers, in addition to the management of their projects, should stay up-to-date regarding what is happening in the clinical industry. The world we live in is changing faster and faster and new technologies have transformed our way of life and our way of working. Clinical Project Managers should be in constant search of opportunities brought by new technologies. But the use of these technologies in clinical projects requires new skills, a high degree of IT knowledge, more statistics and data management capabilities, and change management.

Clinical Trials have already applied Electronic Data Capture since the beginning of this century, but the Risk-Based Monitoring approach has been only in practice since 2013<sup>1,2</sup>. This is already a huge change since data are checked on an ongoing basis and it has been demonstrated that it increases data quality and improves site support<sup>3</sup>.

What does it mean on the Project Management level? Project managers must now embrace risk assessment and be a leader of Quality-by-Design principles<sup>4</sup> during the start-up phase. But they must also ensure that the tools are in place in order to have an ongoing review of the risk, and the data linked to it, set-up at all levels (data management, central lab, IWRS, etc.). Therefore, we need to have the data integration put in place across the entire Clinical Research organisation. This is one of the many challenges our industry is facing. Fortunately, there are some initiatives, such as Transcelerate<sup>5</sup>, to improve automation, data integration and analytics and data quality in Clinical Research.

What is the role of the clinical project manager during a study under Risk-Based Monitoring? The CPM should ensure that the data are reviewed on an ongoing basis and that all risks are identified in a timely manner. As usual, they have to keep the oversight, but it requires a better understanding about data management and statistics and a higher interaction with biometrics.

Which means, now, Clinical Project Managers must not only have management skills but they must also have more IT skills, they must understand what is a database and be able to understand statistics. It is not enough anymore to be a good leader<sup>6</sup>.

Project managers should also ensure that this new way of working is well understood and embraced by all stakeholders, which means some change management skills are necessary as well.

Besides Risk-Based Monitoring, we now have plenty of other sources of data that can be exploited, such as the electronic Patient Reported Outcomes or the electronic Clinical Outcome Assessments. Indeed, now study subjects are really the driver of their data; they can immediately interact with the site staff by reporting all they feel, the medication they are taking, etc., directly via their smartphones, or tablets or wearable devices. Study subjects are more engaged in the data collection and this requires additional training to and from site staff. And, of course, this requires more support from the clinical project managers as well.

Indeed, it requires some supplementary skills during the study set-up: additional vendors need to be contracted (multiple vendors management), and a deep understanding of every device to be used and including having some knowledge about medical device management<sup>7</sup>. Because of the use of wearables, clinical managers should now have an overview of the drug and medical device legislations<sup>8</sup>. What's more - all these devices use study subject's sensitive or private data, so clinical project managers must also ensure that data privacy regulations and data protection are fulfilled for any of the device used<sup>9</sup>.

Additionally, we are also speaking about Real World Data. The use of real-world data (RWD) is a new way to set-up a study and collect data and is something that needs to be considered at protocol development. Even if Clinical Project Managers are rarely part of the study design discussion, they should be able to provide some input into the collection and monitoring of RWD. That is why they need to take all opportunities into account to ensure that the required data will be collected in a timely manner<sup>10</sup>. RWD can be a good way to save time and money. But, again, this will require some knowledge about what can be collected from RWD, how to integrate it in a protocol and this may require some legal knowledge. It is, indeed, even more complex to set-up a study as such.



But, again, this will require some knowledge about what can be collected from RWD, how to integrate it in a protocol and this may require some legal knowledge. It is, indeed, even more complex to set-up a study as such.

And finally, above all, we also now have the possibility to use electronic Informed Consent Forms (eICF). This new way uses IT to ensure study subjects understand what a clinical trial is and what this specific study means for them. Indeed, it has been shown that eICF can increase the study subjects' comprehension and retention of information<sup>11</sup>. This is a huge change for the site, but also for clinical project management. Setting-up such tools is very demanding since you need to ensure that the information is properly presented, know how to conduct the informed consent process, how to document it, how to ensure data privacy, how to track any amendments and re-consent, and such, in every language. So, it requires from the Clinical Project Manager not only scientific knowledge but web design notions as well as IT skills, understanding of animated videos, etc. It is no longer just writing an ICF in accordance with the 20 ICH-GCP principles and local legislation requirements, it is really much more than that!

In conclusion, Clinical Project Managers already wore several hats in the past, which is still the case, but now they need more knowledge and skills to succeed with the additional challenges that new technologies are bringing.



By Nelle Stocquart

## References:

<sup>1</sup> EMA Reflection paper on risk based quality management in clinical trials

<sup>2</sup> FDA Guidance for Industry Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring

<sup>3</sup> Risk-Based Monitoring: A Closer Statistical Look at Source Document Verification, Queries, Study Size Effects, and Data Quality.; Vadim Tantsyura, MS, MA, DrPH, Imogene McCanless Dunn, PhD, Kaye Fendt, MSBS, Yong Joong Kim, MS, Joel Waters, MSCR, MBA, Jules Mitchel, MBA, PhD; *Therapeutic innovation & regulatory science*, Volume: 49 issue: 6, page(s): 903-910 Article first published online: May 25, 2015; Issue published: November 1, 2015

<sup>4</sup> <https://www.ctti-clinicaltrials.org/projects/quality-design>

<sup>5</sup> <https://www.transceleratebiopharmainc.com/>

<sup>6</sup> ECCRT Risk Based Monitoring Course - <http://www.ec crt.com/courses/risk-based-monitoring-0>

<sup>7</sup> Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claim

<sup>8</sup> ECCRT course Medical Device Regulation - <http://www.ec crt.com/courses/medical-device-regulations>

<sup>9</sup> ECCRT course Data Protection in Clinical Research and GDPR in action - <http://www.ec crt.com/courses/data-protection-clinical-research-and-gdpr-action>

<sup>10</sup> Real world data: Additional source for making clinical decisions, Rajiv Mahajan, *Int J Appl Basic Med Res*. 2015 May-Aug; 5(2): 82.

<sup>11</sup> <https://resources.crfhealth.com/electronic-informed-consent/3-ways-electronic-informed-consent-benefits-trial-participants>

<sup>12</sup> FDA Use of Electronic Informed Consent Questions and Answers

# ECCRT Free Newsletter



Visit our website:

[www.eccrt.com](http://www.eccrt.com)

Follow us through our social media:



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Qfor Certified