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MISSION

Through worldwide collaboration, CROES seeks to assess, using evidence based scientific methodology, the various aspects of clinical endourology.

VISION

By applying rigorous scientific evaluation to the field of clinical endourology, CROES will enable all urologic surgeons to bring to their patients the most effective and efficient care possible.

PROJECTS

- Global PCNL study
- Global URS study
- Global Greenlight Laser study
- Global Renal Mass study
- Global NBI study

CONTACT

For more information please contact Sonja van Rees Vellinga (info@croesoffice.org).

AN INTRODUCTION TO THE CROES TEAM

Sonja van Rees Vellinga and Jean de la Rosette

The Clinical Research Office of the Endourological Society (CROES) aims to promote and support high-quality international patient-centered research. A global network of close to 350 centers has been established that collaborates within CROES. The CROES office provides the infrastructure to conduct multicenter studies, including evaluation of the quality of projects, data collection, statistical analysis and preparation of manuscripts[1–3]. At this moment in time we would like to introduce the members of the CROES team who are responsible for all this work.

Sonja van Rees Vellinga is the executive director of CROES. She has been involved with CROES since the beginning. Sonja has studied psychology and graduated in 2001. After working as a career counsellor, she realized her true ambition lay in the field of research. Within CROES she can combine her interest in research with the management of an office and all its aspects. Sonja is responsible for the daily running of the CROES office. She is involved with all steps of the process, from the creation of the database for each new project until the publications come out of the study. Her main responsibilities are to communicate with the Steering Committee, the participants and the sponsors about all aspects of the studies; to prepare meetings; to guide the data managers and to guard the publication process. She also maintains the website and creates the newsletters together with the other members of the CROES team. “What I most like about my job is the diversity of the activities I perform and the clinical setting. Results can be directly translated into clinical practice and we can achieve interesting results in a short period of time”.

Selma Mehmedovic has been a member of the CROES office since 2008. As a health scientist within CROES, her duties are writing parts of protocols, developing and maintaining standard operation procedures (SOPs), coordinating studies according to SOPs, ensuring patient safety, and informing investigators about laws and regulations.

In clinical research, the *International Conference on Harmonisation* (ICH) defines SOPs as "detailed, written instructions to achieve uniformity of the performance of a specific function." SOPs describe specific procedures performed during the conduct of a clinical research study involving patients. SOPs are written in user-friendly language and are designed to function as a manual. Many of the individual SOPs are supplemented by forms, checklists and templates that can be utilized by the site as efficiency tools in the day-to-day responsibilities of clinical research. SOPs help to ensure consistency and efficiency of the CROES office and the investigator’s site. Without SOPs an office/site runs a high risk of Good Clinical Practice (GCP) noncompliance and poor productivity. GCP

is a standard rule within CROES for the design, conduct, performance, monitoring, auditing, recording and reporting of clinical trials. GCP provides us assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. "I would like to put all our investigators worldwide in the spotlight for their hard work; they make it possible with their active participation!!"

Giovanni Pagliuca is the Clinical Data Manager for the CROES Renal Mass, Ureteroscopy (URS) and Narrow Band Imaging studies. After earning his Ph.D. in the United Kingdom, Giovanni served as a clinical data manager and data analyst for several institutions in England, and recently joined CROES in Amsterdam. His main areas of expertise are clinical data management and medical statistical analysis. Within CROES, Giovanni is responsible for the data validation, case report form design, regulatory development, and communication with centers for most of the clinical studies currently open. Clinical study coordination is an area that Giovanni would like to explore further in the future, supporting the CROES office in its wide range of clinical research activities and providing a valuable service to the endourological scientific community.

Hiren Sodha is the Clinical Data Manager for the CROES Greenlight Laser study. He is combining the work for CROES with a fellowship at the AMC University Hospital in Amsterdam, where the CROES office is based. Hiren previously worked as a chief urologist at the RG Stone Urology Center. His extensive knowledge and experience in the field of urology is of great importance for the design of the studies. "I feel honored to work with CROES, a stage for global multicenter studies and body where authentic knowledge and skills in the field of endourology are showcased. It is a highly responsible position to be a part of one of the highest standards of clinical research in the field of endourology. My enduring idea is to spread the CROES vision & mission to every center dedicated in the field of endourology."

Dedan Opondo started working as a clinical researcher with the team at CROES in 2009. He participates in various phases of the global studies namely; study design, data management, statistical analysis and preparation of publications from the CROES office. His work therefore traverses the whole research trajectory of a typical study in the CROES.

"Working in a multinational research setting is both exciting and challenging. The Clinical Research Office of the Endourological Society (CROES) offers an interesting platform for anyone interested in large database research. Working along the lifecycle of the studies requires great collaboration within a team. At the CROES office, we have a highly consultative team. Regular meetings enable us to make decisions allowing us to operate with high dynamism and achieve results in short periods of time."

CROES is quite ambitious. We are confident, however, that with this fine team we will be able to reach the high goals set: to provide the absolute best, least invasive, quality of care for all our patients.

References

1. de la Rosette J, Gravas S. Quality and transparency in CROES research projects. J Endourol 2010;24:317–319.
2. de la Rosette J, Gravas S. Guidelines for CROES publications. J Endurol 2010;24:167–169.
3. van Rees Vellinga, de la Rosette J. The CROES data management system: A glimpse behind the scenes. J Endourol 2011;25:1–5.

- The global PCNL observational study was closed in December 2009.
- The Global Ureteroscopy study and the Global Renal Mass study were closed for initiating new sites in January 2011.
- The Global Greenlight Laser observational study was closed for initiating new sites in April 2011.
- Ongoing projects are: the randomized study on Narrow Band Imaging versus White Light Imaging.
- Projects in preparation are: A randomized study on Focal Therapy for Prostate Cancer
- For further information please visit: www.croesoffice.org or contact the Executive Director of CROES, Mrs. Sonja van Rees Vellinga (info@croesoffice.org).