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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

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QUALITY AND TRANSPARENCY IN CROES RESEARCH PROJECTS

Jean de la Rosette and Stavros Gravas

CROES demonstrates its commitment to the support and promotion of endourology and emerging technologies within the Endourological Society by organizing, structuring and favoring well-coordinated, high-quality and patient-centered research in a transparent way. Within this frame, CROES has taken initiatives to enhance the quality of research projects including:

1. *Data transfer to a safe data management system:* Data of the CROES clinical studies are collected centrally with the help of a web-based data management system. Only participants with a valid username and a password, and access to the study of interest are able to enter data into this system. Dedicated data managers are responsible for checking and securing all incoming data. This centralized database will facilitate statistical/epidemiological support of the projects.
2. *Data transfer agreement:* A data transfer agreement is provided between each principal investigator and CROES. This agreement defines the obligations and rights of each involved party regarding the use of data. At present, the final form of this agreement is under full preparation; after completion, it will be published in *Journal of Endourology* and uploaded on the CROES website.

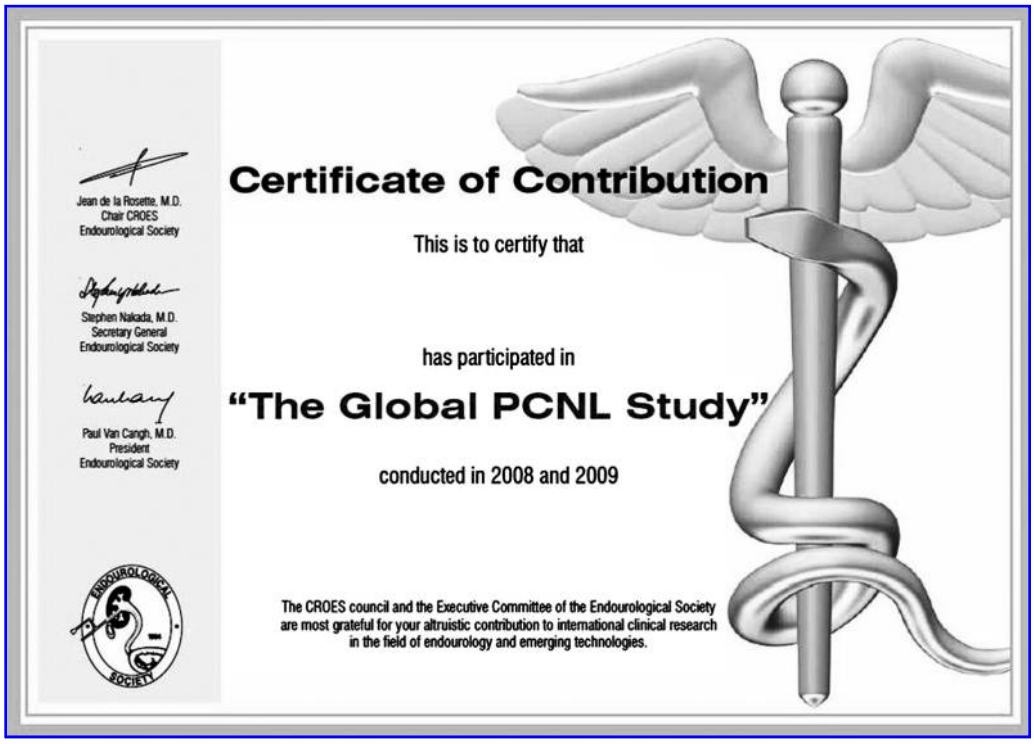

FIG. 1. Example of CROES certificate.

3. The need for Institutional Review Board (IRB) approval: All research undertaken by CROES' approved investigators is subject to the rules set forward by (inter)national health care authorities. Therefore, IRB approval or a letter from the principal investigator of the study site assuring the quality and ethical standards of data collection is requested to participate in the CROES' projects. The chairman of the participating department and the primary investigator should be responsible.

4. Independent audits: In order to validate the accuracy of all study data, the possibility of an independent audit of submitted data is implied in every CROES agreement. Self-reported data characterize the initial CROES' studies; therefore, there is the need to monitor and validate the data by an independent source. The CROES' council has discussed this issue with the Executive Council of the Endourological Society; the conclusion is that an independent audit will best meet the requirements. Accordingly, the chairperson of the audit committee will be appointed by the Secretary General of the Endourological Society. In addition, CROES will inform each participating center that an audit is integral in every CROES contract; failure to allow an audit to proceed will result in removal of the institution's data and investigators.

5. A contribution certificate: At the end of each study, participating centers will receive a certificate signed by the Chairman of CROES, the Secretary General and the President of the Endourological Society (Fig.1). This certificate, in recognition of a minimum number of cases contributed to a given study, will certify the valuable participation of each center in the specific project and will recognize its contribution to international clinical research in the field of endourology. The certificate will be sent to the institution at the end of the study, upon receipt from that institution of a signed statement that the reported data are complete and correct.

As stated in a recent editorial in *Journal of Endourology:* "We must ensure the ethical and scientific integrity of clinical research globally, promote harmonization of international research.....and reach the ultimate goal of our professional career: to provide the absolute best, least invasive, quality of care for all patients. The time is now – with CROES, the ability is yours."[1]

Reference

1. de la Rosette J. A platform for global endourological research. J Endourol 2009;23:1551–1553.

- The Global PCNL observational study was closed on December 31, 2009.
- Ongoing projects are: the Global Greenlight Laser observational study, the Global Ureteroscopy study, and the Global Renal Mass study. At present a randomized study on Narrow Band Imaging versus White Light Imaging is in preparation.
- For further information please visit: www.croesoffice.org or contact the Office Manager of CROES, Mrs. Sonja van Rees Vellinga (info@croesoffice.org).