



DOI: 10.1089/end.2011.1507

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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).



## GUIDELINES FOR IMPLEMENTATION OF THE AUDIT COMMITTEE

*Jean de la Rosette and Stavros Gravas*

CROES demonstrates its dedication 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.<sup>1</sup> Though all participating centers contribute in good faith and to the best of their ability, the self-reported nature of data may harbor some limitations, underlining the need for a mechanism to monitor and validate the collected data and eventually to control and secure the quality of the results coming from the studies.

In light of all these considerations, the CROES Council and the Executive Board of the Endourological Society have taken the initiative to install an Audit Committee for CROES studies aiming to enhance the quality of research projects.

It is well known that since its founding CROES has committed itself to transparency in communication with all the participants in CROES studies. All relative information has been published, including publications guidelines and the data transfer agreement.<sup>1-3</sup> Within this frame, the CROES Council has prepared guidelines to present in a transparent way the position of the Audit Committee:

### *Guidelines Audit Committee*

- a. The Audit Committee will be comprised of six international members who are of good standing and who are members of the Endourological Society.
- b. The term for each member is 3 years, renewable for a period of 3 years.
- c. The Audit Committee provides the necessary independence to the data collection.
- d. The Audit Committee prepares guidelines that clearly describe the audit process and the actions of the committee.
- e. The Audit Committee prepares, executes and supervises an audit in the format agreed upon.
- f. In agreement with the "transfer of data agreement" signed by all Primary Investigators of each study, all data provided by each site will be audited electronically. On-site audits should be limited and will only be included if deemed necessary.
- g. The Audit Committee defines and classifies the outcomes of the audit as follows:
  - Accurate/objective data*: Data OK
  - Incomplete data*: Data with missing values (not requiring any additional actions unless missing data is critical)
  - Alerting data*: Outliers (see below) or when a significant difference in the enrollment rate from the same center is observed
  - Unverifiable data*: Inability to reply to the electronic/on-site audit
- h. The Audit Committee reports on the outcomes of each study to the Steering Committee and the CROES council.

- i. The Steering Committee will discuss and decide upon the implementation of the recommendations made in the report as provided by the Audit Committee.
- j. This decision needs to be endorsed by the CROES Council in order to receive final approval.
- k. Centers that are excluded from the analysis of the data will be informed after auditing (electronically and/or on-site) that their data did not meet the high-quality standards of a CROES study; therefore, a certificate of participation cannot be given.
- l. In case of a disagreement regarding issues related to these guidelines the CROES Council would make the final decision. In the rare case in which a further appeal is made, then the issue will be placed before the Executive Council of the Endourological Society.
- m. In “Methods” of each paper the audit process needs to be mentioned, including the implementation of the recommendations.

### *Further information*

The first Audit Committee is comprised of Glenn Preminger (United States) as chairman, and Peter Alken (Germany), Tomonori Habuchi (Japan), Andreas Skolarikos (Greece), Hessel Wijkstra (The Netherlands) and Chang-Jun Yin (China) as members. The members of the Audit Committee represent a good balance between technical background, seniority of high standing and junior spirit.

The unique web-based Database Management System includes some special features that enable data to be audited electronically without jeopardizing the ease of collecting and documenting data. In addition, some centers will be selected to have an audit of their data on-site, either randomly or based on the information provided. For example, a center without complications (outlier) or with an enrollment rate that significantly varies during the 12-month recruitment, indicating a potential selection of cases.

Since CROES projects need long-term cooperation from participants, it is essential to arrive at a mutual robust agreement that will secure the ethical and scientific integrity of clinical research globally resulting in the absolute best, least invasive, quality of care for all patients. CROES clearly states its policy regarding the quality control of data through the Audit Committee in order to prevent premature agreements and avoid insufficient data collection and late misconceptions. The time is now – with CROES, the ability is yours<sup>4</sup>.

### **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 Endourol* 2010;24:167–169.
3. de la Rosette J, Gravas S. Data transfer agreement form for CROES research projects. *J Endourol* 2010;24: 501–504.
4. de la Rosette J. A platform for global endourological research. *J Endourol* 2009;23:1551–1553.

- 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.
- Ongoing projects are: the Global Greenlight Laser observational study and the randomized study on Narrow Band Imaging versus White Light Imaging.
- The next meeting of the Steering Committees will take place in Paris on June 8, 2011, prior to the Challenges in Endourology meeting.
- For further information please visit: [www.croesoffice.org](http://www.croesoffice.org), or contact the Executive Office Manager of CROES, Mrs. Sonja van Rees Vellinga ([info@croesoffice.org](mailto:info@croesoffice.org)).

