Ethical GmbH: Uppsala Clinical Research Center provides Feedback on its Use of the Ethical eAdjudication® Platform to support the Clinical Endpoints Adjudication Process

Uppsala Clinical Research Center (UCR), a top Academic Research Organization based in Sweden, shares its experience in using the Ethical eAdjudication® cloud-based platform to manage the central assessment of Clinical Trial Endpoints by an independent CEA (Clinical Event Adjudication) Committee.

BASEL, SWITZERLAND and UPPSALA, SWEDEN (PRWEB) December 09, 2015 -- The review published earlier this year by S. Krumholz-Bahner et al. in DIA's Therapeutic Innovation and Regulatory Science, I-9 Journal has highlighted the key role endpoint adjudication plays in the approval of new therapies by regulatory authorities. The article states that "in 2013 and 2014 a total of 35 new molecular entities (NMEs) were approved by the US Food and Drug Administration (FDA) and 88 [by the] European Medicines Agency (EMA). Notably, an adjudication method [was] used for the primary endpoints of their phase III development program in 69% of the NMEs approved in the United States and 41% of EMA approvals used […].

Drugs developed for oncology and endocrinology typically used an independent review committee [also referred to as an Event Adjudication or Clinical Events Committee] in line with recommendations made in relevant regulatory guidance, whereas nervous systems, antivirals, and vaccines drugs typically did not. Central reading was most frequently used for efficacy endpoints or in a combination of efficacy endpoints and safety measures. Overall, approximately 20% to 30% of the primary endpoints analyzed in the US/EMA documentation were classified as subjective endpoints that were based on clinician-dependent (and subject-dependent) assessments. The remaining 70% to 80% were more robust endpoints that were reviewed by a central committee and/or were based on objective (measurable) endpoints, including laboratory tests."

Because of the growing importance of Endpoint Adjudication in clinical projects, CEA-chair Claes Held, MD, PhD, Associate Professor states, "Independent Endpoint Adjudication through a transparent and well controlled process is an essential part of the efficacy and / or safety analysis in a clinical trial because it helps to minimize variation in the interpretation of outcomes and events ensuring high quality and reliability of the results. Therefore, it is important that the process supporting the adjudication tasks is lean, well organized and reduces the administrative burden for all stakeholders involved while ensuring a high scientific and regulatory integrity. Since the traditional paper-based process of performing peer-reviewed adjudication is cumbersome, time consuming and prone to errors (e.g., loss of dossiers), this approach was not really an option for UCR. We evaluated several alternative approaches to adjudication, looking for user-friendly innovative and efficient solutions.

About one year ago we have deployed the Ethical eAdjudication® Platform and have systematically used it in several clinical trials involving endpoint adjudication. This platform has allowed us to move from a manual to a more standardized and electronic "paperless workflow".

Another advantage of the Ethical eAdjudication® Platform that both UCR and study-sponsors appreciate, is the role-based management of permissions and related workflows, simplifying administration of the system. This allows real-time, direct and controlled access to the study status, data, documents and adjudication decisions".

As the Ethical eAdjudication® Platform is a fully validated system one concern expressed during the roll-out of the system was that flexibility and agile adaptation to study requirements and timelines could be compromised.

UCR Director Clinical Research, Raf Lemmens was pleased to observe that “the flexibility of the Ethical eAdjudication® Platform and the great support given by the Ethical GmbH team allowed us to rapidly tailor the “generic” Platform workflow to the study-specific workflow needs of the study and adjudication teams. In addition, the project metrics and availability of built-in quality control enables us in UCR and also the sponsors of the studies to exercise the oversight that GCP demands.”

“We are really proud that our new eAdjudication solution has helped UCR to improve efficiency while maintaining high quality in the Adjudication process. To work with such a renowned group and having been able to contribute to a further improvement of their services makes us feel very proud." said Mimmo Garibbo, Director of Ethical GmbH.

About eAdjudication
a cloud portal designed to support Study Leaders, Central Review Committee Members (e.g. DSMB, efficacy endpoint review), Q.A. Staff and Sponsors across the whole adjudication process.

Main features include the MANAGEMENT OF DATA / DOCUMENTs related to EVENTs, MANAGEMENT OF THE INDEPENDENT COMMITTEE MEMBERS, ENDPOINT ASSESSMENTS COLLECTION, REPORTING & DATA EXPORT. The portal is usually provided as a fully managed service including the hosting, technical management, validation (CSV / 21 CFR Part 11 compliance), training & day-to-day technical support. It can equally be used for large as well as smaller studies, by small-sized as well as large companies or academic groups.

About UCR
Uppsala Clinical Research Center (UCR) is a non-profit academic clinical research organization providing services to academic researchers and pharmaceutical and medtech companies in Sweden and internationally. UCR is an independent entity within Uppsala University and Uppsala University Hospital. UCR offers all services needed to conduct a clinical study, from protocol to clinical report, having special expertise in adjudication of clinical events. UCR was Sweden’s first Center of Excellence for National Quality Registries under the National Board of Health and Welfare and is, as the host of approximately 20 national quality registries, a leading organization for quality control and evaluation of new therapies in health care. UCR also includes Uppsala Biobank with infrastructure for collection and storage of biological materials and UCR Laboratory, an accredited biomarker laboratory.

About Ethical GmbH
Ethical GmbH is a company, based in Basel Switzerland, exclusively focused on eClinical cloud software & services to support life science & drug development. Main solutions offered by Ethical include eAdjudication for Clinical Endpoint Adjudication and e-CRF the eClinical platform for Electronic Data Capture and Data Management.

Ethical is a startup owned by GM Servizi, a software house based in Italy, that since 1997 is supporting with its software solutions about 300 international trials with more than 10,000 investigational sites and hundreds of thousands patients.

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