

The Engaged Database (TED)

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MUNICH, GERMANY, April 18, 2018 /EINPresswire.com/ -- The Engaged Database (TED), a benchmark sample of anonymised clinical study audit observations, compiled according to EMA inspection database categories.

The Engaged Database (TED) allows users to compare their own audit observations, against a large number of other audit results, grouped according to the European Medicines Agency (EMA) categories and sub-categories and classification criteria. The data is fully anonymised using a numbering system for each audit, protecting the identity of the auditor/auditee. TED reports plot user audit observations against other benchmark audit results of the same audit type, already in the database. In addition, the report shows the percentage of audit reports with findings in this category and gives an average compliance index of the severity of observations. Filters such as clinical phase, geographical location, or a specific observation, can be used to tailor the benchmark sample further. This provides a global resource for all pharmaceutical, biotechnology and medical device companies, as well as academia. Users can see in no time where their audit result stands, compared to a larger volume of audit results already entered.

TED is owned and managed by Dr. Barbara Heumann, who owns the independent auditing company, GXP Engaged Auditing Services. TED has a governance group made up of clinical research professionals, from all over the world, who ensure that the process to collect and capture audit data is sound and based upon robust quality criteria and in full compliance with scientific, legal and ethical standards.

TED is a smart solution saving resources and helping to avoid research and development project failures by allowing users to find out early how their audit programme measures up against those of other companies. What do the results really mean and what can one learn from them? Speaking at the recent launch of The Engaged Database (TED), Dr. Barbara Heumann said, "TED can help large companies avoid a bias when interpreting audit results, whilst allowing smaller companies to benchmark even if they have only very few audits of one type. Therefore, potential risks can be identified which can lead to a more informed decision on a corporate level." She summed up by saying, "We will be exhibiting TED at SQA 8-13 April, DIA Europe 17-19 April, DIA China 23-25 May and DIA Boston 24-28 June and we look forward to demonstrating and promoting this excellent tool with you there, as well as within our sponsor networks worldwide."

For further information, see <u>www.TheEngagedDB.com</u> or contact Dr. Barbara Heumann, The

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