"Biomarkers" in medical imaging are the key to detecting and treating cancer

Press Release

MEDIAN Technologies has signed a landmark contract with the top pharmaceutical company SANOFI for medical image interpretation and management in a new phase II study on small cells lung cancer.

For the first time in Clinical Trials: the use of software solutions for image interpretation, harmonization and standardization will be deployed at all 65 investigator sites and independent central reviewers.

Sophia Antipolis, France, February 1st, 2012 - MEDIAN Technologies (ALMDT), a leading services provider for image interpretation and management in oncology clinical trials, and software provider for medical imaging, announced today the signature of a landmark contract with the top pharmaceutical company SANOFI for the interpretation and end-to-end management of medical images in a phase II study on small cells lung cancer.

For the purpose of the study, imaging data will be acquired in 65 investigator sites located in 15 countries. Anticipated total enrollment is 150-200 patients.

MEDIAN's innovative imaging data management concept as proposed to SANOFI includes the deployment of the MEDIAN LMS[1] platform at all 65 investigator and independent review sites.

Thereby, for the first time in a clinical trial, image interpretation tools will be harmonized and standardized among all the investigator sites and the independent reviewers involved in the study. The objective is to reduce reading variability and discordance issues in image interpretation; these are known to impact negatively the quality of clinical trials outcomes, leading, in some cases regulatory agencies, to reconsider clinical trials results.

Using MEDIAN LMS, all investigator sites will benefit from a software platform dedicated to the evaluation of patient's response to cancer therapy providing automated and semi-automated image processing capabilities in a well-standardized workflow. The sites will be able to conduct RECIST 1.1 criteria-based evaluations in accordance with the existing international recommendations. The end-to-end image management will be carried out through MEDIAN CTIS[2]. Notably, the real-time electronic imaging data transfer from investigator sites to independent review sites will allow the independent reviews to be processed faster and with a more efficient management of queries on missing or erroneous data.

"Thanks to this first collaboration with SANOFI, we are now supporting 4 of the 10 major pharmaceutical and Biotech companies. We are eager to start this new partnership with SANOFI, it is a very important contract and an excellent illustration of the emergence of a new paradigm in terms of clinical trial image management", says Jerome Windsor, VP Business Development at MEDIAN

[1] See Appendix
[2] See Appendix

Technologies. *"Until now, the optimal use of images has long been restrained due to the high interpretation variability. MEDIAN's solutions increase significantly the accuracy of data interpretation; they also create new perspectives for pathology follow up, and this is for the benefit of the patients".*

For the record, MEDIAN Technologies is ISO 13485 certified – ISO 13485 is the internationally recognized quality standard for the medical device industry. MEDIAN LMS applications received FDA approval in 2007 and are class IIa CE marked since 2010. LMS are used by key opinion leaders in over 100 centers in Europe, the USA and, most recently, Australia and New Zeeland. CTIS includes a set of services dedicated to image management during clinical trials and is based on MEDIAN LMS technology. MEDIAN CTIS was launched during ASCO 2011.

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About MEDIAN Technologies: Based in Sophia Antipolis, MEDIAN was founded in 2002 by Fredrik Brag (Current CEO), Gérard Milhiet and Arnaud Butzbach. The company has a staff of 40, over half of whom work in R&D, and has a subsidiary in the USA.

MEDIAN Technologies offers solutions and services for diagnosing and monitoring cancer patients for clinical trials market in oncology, its priority market, and the patient care market. MEDIAN a collaborated with institutes at the cutting edge of medical imaging, among which the French National Institute for Computer Science and Control (INRIA), Chicago University and the Swiss Federal Institute of Technology in Lausanne, Switzerland (EPFL).

MEDIAN Technologies has been present in the market since 2007 through direct and indirect sales of its LMS solutions and alliances with specialist cancer centers in Europe and the USA.
For more information on MEDIAN, please visit: www.mediantechnologies.com

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APPENDIX : MORE ABOUT MEDIAN TECHNOLOGIES SOLUTIONS AND SERVICES

About LMS (*Lesion Management Solutions*)

Lesion Management Solutions (LMS) detect, evaluate and follow-up automatically and semi-automatically lesions identified in computed tomography (CT) scans. LMS provide response criteria that are utilized for the evaluation of patient response to therapy (such as lesion diameter); they also perform automated measurements of advanced lesion parameters (such as volume, density…), thus allowing the implementation of advanced imaging biomarkers. LMS automation capabilities result in image reading standardization and interpretation variability decrease.

Lesion Management Solutions are compatible with all types of CT scanner. They can be integrated into heterogeneous IT environments and easily deployed at sites with very diverse equipment and software configurations.

The MEDIAN Technologies LMS are "software as a service" (SaaS) products; they are web-based, fully distributed and available anywhere in the world. They are therefore available without any geographic constraints; this represents a key advantage for multicentric clinical trials.

About CTIS (Clinical Trial Imaging Services)

CTIS is a package of innovative services that optimises the use of medical images in oncology clinical trials. CTIS is targeted to the various stakeholders involved in trials including investigator sites, independent reviewers and sponsors. The CTIS package includes four kinds of services that can be customized per trials:

1. Management of investigator sites : site qualification, site training, implementation of infrastructure for onsite image reading, onsite quality control, optimization of imaging data workflow,
2. Independent review services, double reading and adjudication,
3. Centralized databases and on-demand functionalities, sponsor access : project dashboards, data mining, access to all images and data via MEDIAN LMS
4. Advanced reviewing services providing advanced imaging biomarkers.

CTIS is based on the LMS core technology and provides concrete solutions to frequently-observed imaging problems in oncology clinical trials: variability in image interpretation, censoring bias, difficult implementation of advanced imaging biomarkers, complex workflows and management of image databases.