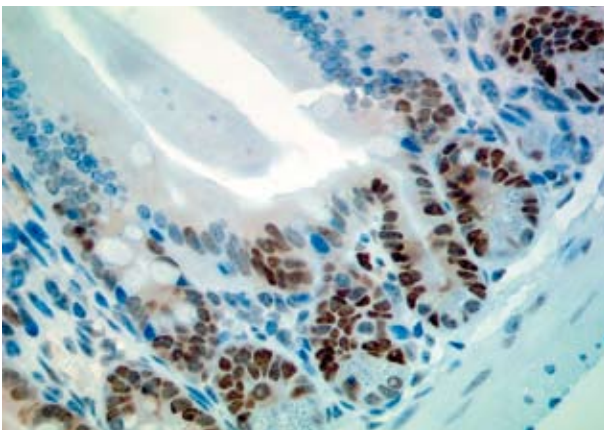


Definiens eCognition Accelerates Safety and Efficacy Studies

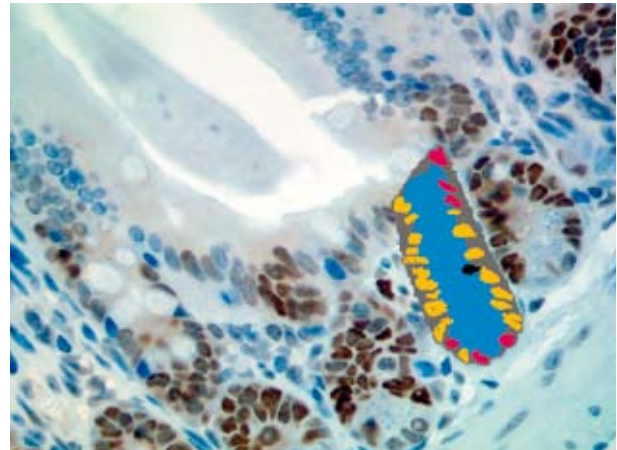
Business Challenges

At Novartis, the preclinical pathologists are under enormous time pressure assessing the safety profile of a drug candidate to accelerate FDA approval. The safety assessment is time-critical since the patent protection marches tirelessly towards expiration and the registration dictates a comprehensive set of preclinical studies. "There is a critical need to get more accurate data faster," says Dr. Elke Persohn, Head of the Cellular Imaging Group at SP&A, Pathology, at Novartis Pharma AG in Basel, Switzerland.

All preclinical studies are performed under the umbrella of the SP&A, the Safety, Profiling and Assessment branch at Novartis. "Given the high cost of failure in drug development, it is crucial that we have tools in place that provide high-quality information about drug targets" says Dr. Persohn. In her team, cell proliferation and immunohistochemistry studies are of major interest and counting of positive and negative stained cell nuclei within specific regions of interest is a necessary task. Until 2003, this has been performed manually or semi-automatically by selecting the regions of interest with the computer mouse and manual or automatic counting of the proliferating cells. However, this was very time consuming. "There was clearly a need to fully automate the process," says Dr. Persohn and adds: "Beside substantial time savings on the way to FDA approval, with a fully automated process more sections/images can be analyzed thus producing more robust results".



Identification of crypts and determination of the proliferation index in the jejunum of rat. BrdU staining of proliferating cells.



Identification of crypts and determination of the proliferation index in the jejunum of rat.

Crypt detection with eCognition (ROI, blue) and counting of positive nuclei (yellow) and negative nuclei (red).

Definiens' Solution

Definiens' technology is now a critical tool at Novartis preclinical site SP&A. A new generation of image analysis software is now available on the market that can fully automatically extract and quantify areas and structures of interest in histopathological images. "eCognition solved our problem to automatically detect small intestine crypts and count proliferating and non-proliferating cells which was not possible with other software solutions," said Dr. Persohn.

The automated image analysis allows repeatable and standardized counting of cell nuclei and crypt area in one quarter of the time. In a 13-week oral toxicity study in mice with 180 animals and investigation of cell proliferation a total of 9000 images have been evaluated. Instead of 16 weeks with manual counting only 4 weeks with eCognition were needed.

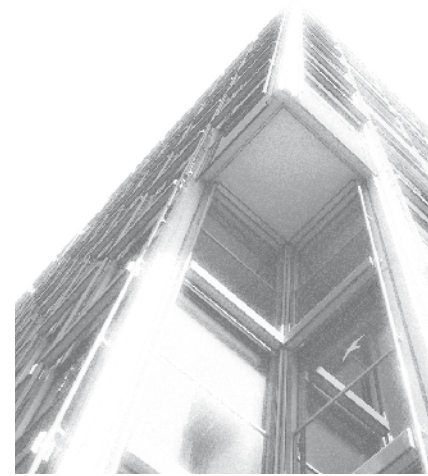
Definiens' eCognition allows a highly significant and sensitive detection of treatment-related effects, which are comparable to semi-automated and traditional methods. But, in addition to these time-consuming and subjective measurements, Definiens' eCognition combines all advantages of automated methods, including reproducibility, speed and around the clock operations.

Benefits

eCognition is a fully automated image analysis system that allows us to increase the number of measurements thus producing more objective and robust results. The enormous time saving potential of eCognition increases the productivity and efficiency of pathologists. Furthermore, eCognition provides quantitative data faster and more accurate.

ABOUT DEFINIENS

Definiens is a global leader in providing Enterprise Image Intelligence solutions and services that enable its clients to harness all relevant information from digital image to support fast and accurate decision making crucial to its business process. Definiens' products are built on its Cognition Network Technology that represents a quantum leap in the realms of digital image analysis. Our products are offered across chosen markets, initially focusing on Earth Observation/Remote Sensing (EO/RS) and Life Sciences. Definiens offers advanced and robust image analysis solutions to accelerate the drug discovery, development, and diagnostics processes in life sciences, and perform satellite and aerial image classification more intelligently, more accurately, and more efficiently than traditional methods. Definiens has customers worldwide in the areas of Life Sciences and Earth Observation/Remote Sensing (EO/RS), including leading companies, academic centers, and government agencies. Founded in 1994 by Nobel Laureate Prof. Dr. Gerd Binnig, Definiens is a multi-national organization with headquarters in Munich, Germany and offices in Boulder, Colorado and Boston, Massachusetts. For further information regarding the company and its products please visit www.definiens.com.



Headquarters:

Definiens AG

TrappentreustraÙe 1

80339 München

Germany

Tel. +49 (0)89 231180-0

Fax +49 (0)89 231180-90

info@definiens.com

www.definiens.com