

# Medical Imaging

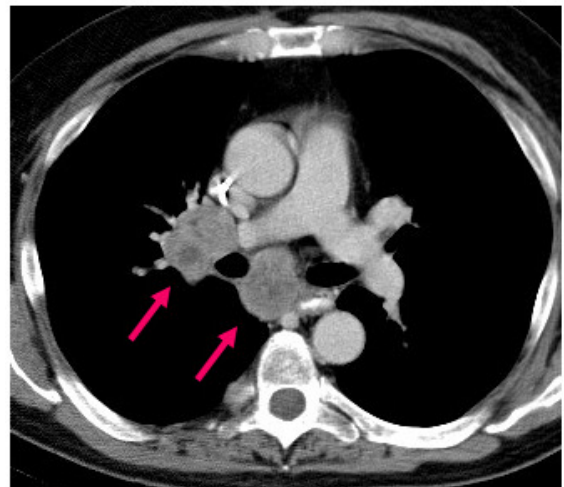
## Experience with Non-Hodgkins Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL)

Perceptive continuously seeks to enhance its knowledge of NHL and CLL clinical trial needs based on regulatory feedback, Sponsor needs and the ever evolving requirements of oncology clinical trials. Perceptive's NHL/CLL Product Program supports all accepted NHL and CLL assessment criteria offering a flexible yet robust solution to support your NHL or CLL clinical trial.

### NHL/CLL Expertise at Perceptive

- Broad medical expertise across radiology and oncology including in-house radiologists and oncologist as well as scientific advisors with expertise in NHL/CLL
- Medical writers with an expertise in NHL/CLL for efficient, detailed-oriented charter development
- A dedicated NHL/CLL Product Team with representation by Medical, Medical Writing, Oncology Program Management and Analysis Application Development who support the development of Perceptive's Core NHL/CLL Smart Applications
- An NHL/CLL Product Team Scientific Advisor with expertise in software development
- Assessment criteria guidance provided by Perceptive Scientific Advisor, Dr. Bruce Cheson, author on all four accepted assessment criteria articles for NHL and CLL (IWG-1999, IWG-2007, NCI-WG for CLL 1996, IWCLL-NCI-2008). Perceptive is working with Dr. Cheson to develop consistent guidelines on applying the NHL/CLL criteria design. This enhances Perceptive and Sponsor understanding of the criteria to further harmonize Sponsor clinical trials at the site and at independent review level, as well as across clinical trials
- Project Managers specifically trained on the NHL/CLL and the project management considerations for these disease indications

- Regulatory leadership provided by Dr. George Mills, VP, Perceptive Medical Imaging & Regulatory Affairs, former Division Director of Medical Imaging and Hematology Products in the Office of Oncology Drug Products, FDA



### 'Smart Applications'

- Perceptive develops and validates analysis applications to enhance the review process and workflow for studies using the NHL/CLL analysis criteria further enhancing the validity of Sponsor data

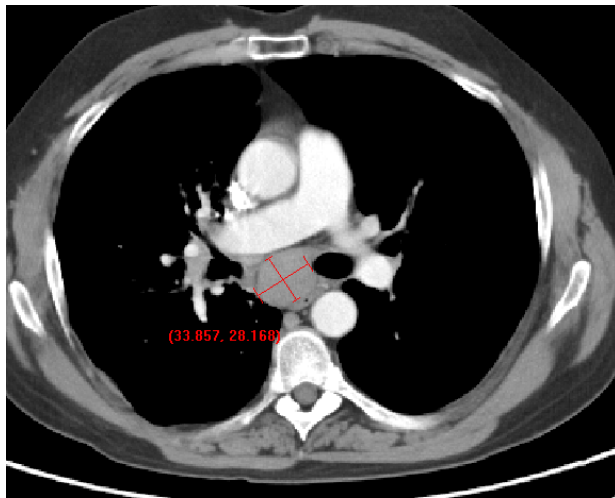
*The Perceptive Smart Application includes:*

- Electronically and dynamically linked electronic case report forms (eCRF) and images
- Automatic logic and quality control checks, significantly reducing the chance of human error
- Software which alerts the reviewer if the assessment he/she made is in violation to the rules defined in the charter
- Independent and unbiased assessments without need for support from another individual
- Electronic audit trail

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### Additional Services to Support Your NHL/CLL Clinical Trial

- Study design support
- Protocol development support
- Support for meetings with regulatory authorities
- Independent Review Design and Charter Development
- Training on applying NHL/CLL assessment criteria
- Analysis criteria specific consultation with Perceptive Medical staff and Scientific Advisors



### Perceptive at a Glance

Perceptive Informatics brings together exceptional clinical knowledge, experience and leading-edge technology. As the industry's leading eClinical solutions provider, we combine these qualities into a portfolio of business support applications and complementary services that optimize the process of product development and commercialization. Our customers are forward-thinking pharmaceutical, biotechnology and medical device companies, CROs and associated service providers.

Our versatile, comprehensive eClinical suite is built upon six areas, each of which makes extensive use of innovative technology:

**ClinPhone RTSM ■ Imaging ■ CTMS  
EDC ■ ePRO ■ Solutions**

Each element of our eClinical suite is designed to deliver practical and tangible results—decreasing the time, cost and risk associated with the development and launching of new products.

It is reassuring to know that our professionals have a combined clinical and technology background. This means that our products and services accommodate the needs of the regulated world (such as computer system validation and 21 CFR Part 11).

Our tried and tested solutions are used by many of the world's leading pharmaceutical companies.

**To learn more about how our solutions can help you, please contact us at [info@perceptive.com](mailto:info@perceptive.com).**