

Integrating Clinical Images into the Data Review Process

(PP07)



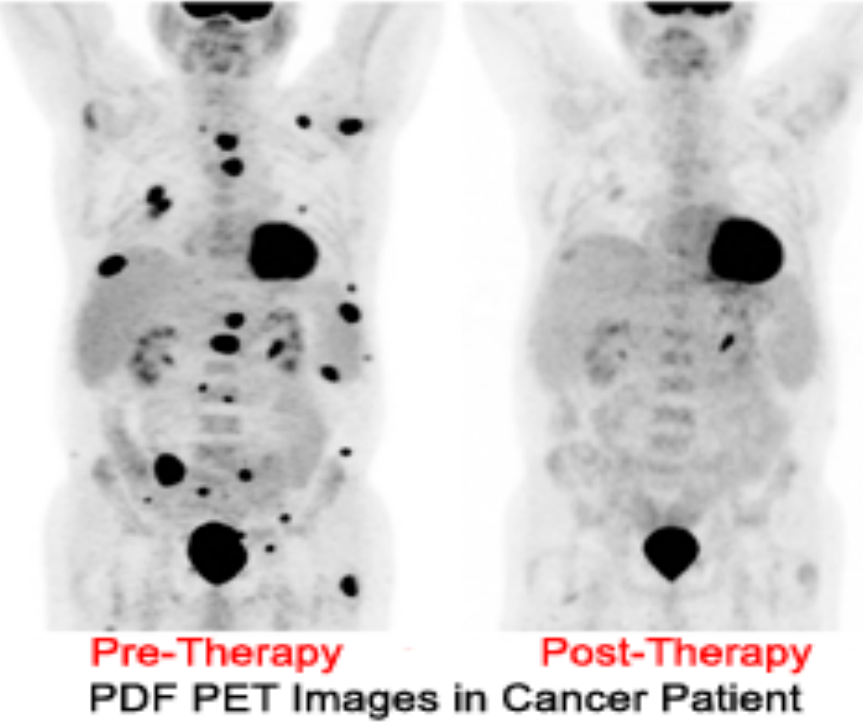
Kellie Riley

Data Acquisition Specialist
Clinical Data & Information Sciences pRED – F. Hoffmann-La Roche Ltd

1.IMPORTANCE OF CLINICAL IMAGES IN DATA REVIEW

During recent years the use of images (for example MRI, f-MRI, PET) is becoming much more frequent across therapeutic areas (e.g. oncology, CNS).

90% of all oncology studies have an imaging component. Very often the primary endpoint is based on imaging information. Imaging plays an increasing critical role in oncology drug development, as it allows us to understand what is happening in the tumor, in response to treatment, in humans, on an ongoing basis. Only imaging technologies can provide such detailed information in a non-invasive way.

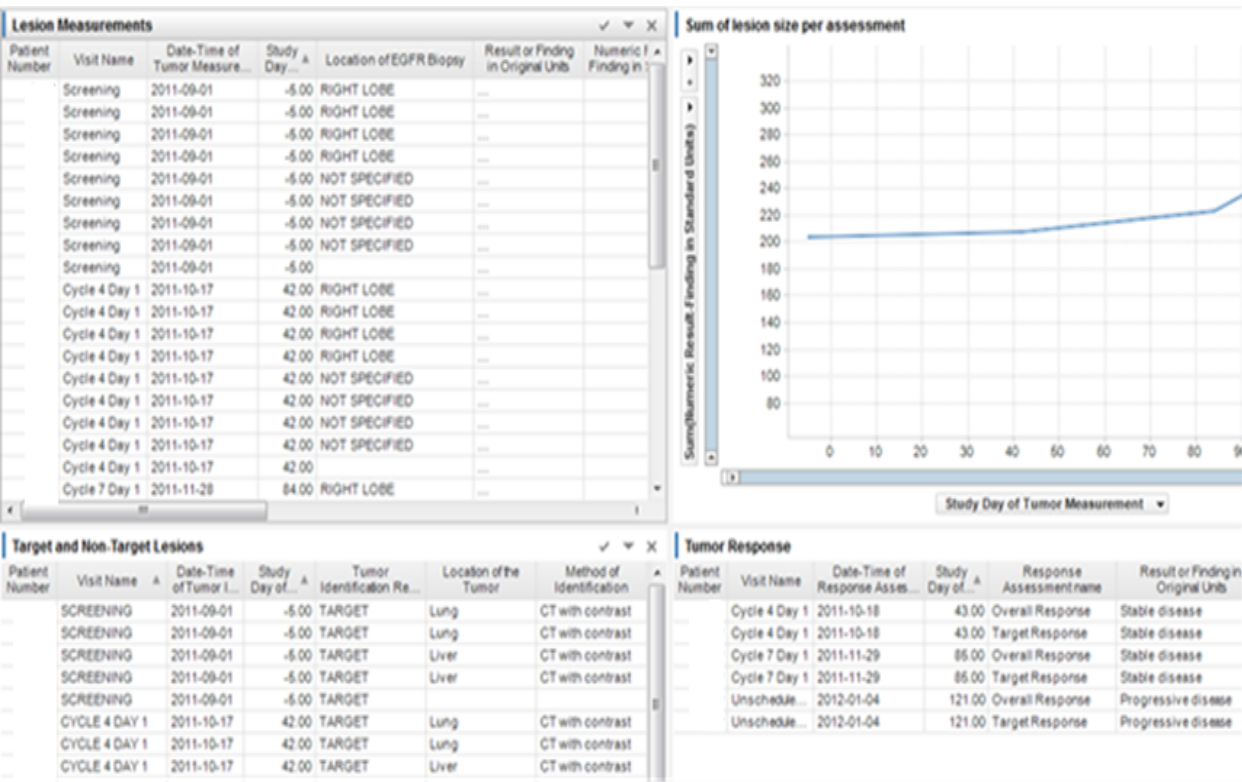


In the poster presentation we will graphically show the implementation of the Spotfire® interface between numeric imaging data, the images themselves and how we ensure quality of data by combining with all associated eCRF assessment information.

2.MEDICAL DATA REVIEW AND VISUALISATION

At Roche's pRED department (Pharma Research and Early Development), the clinical data generated in a study are entered in RAVE™ (electronic case report form). The data are extracted and transformed into standardized SDTM-based formats, which can then be reviewed using for example TIBCO Spotfire®. This tool is providing rapid data access with data structures tailored for medical data review and allows for exploratory data evaluation using interactive graphical displays.

Figure 1: Demonstrates a view of numeric imaging and eCRF assessment data. Using TIBCO Spotfire® One can easily create visualisation templates that enables viewing, summarizing and graphical representations of specific data of interest which can be used across studies.



3. IMAGE REPOSITORY

Clinical imaging can be an asset for better understanding the efficacy of a drug. It is important to get access to study images and results in order to maximize information for decision making and designing further clinical development steps. Because of the size and the format of images and image meta data, the information can not be loaded to e.g. Rave. In pRED Roche we are using MIRA™ (Medical Image Review and Analysis) as a repository for clinical images, measurement data and study documents.

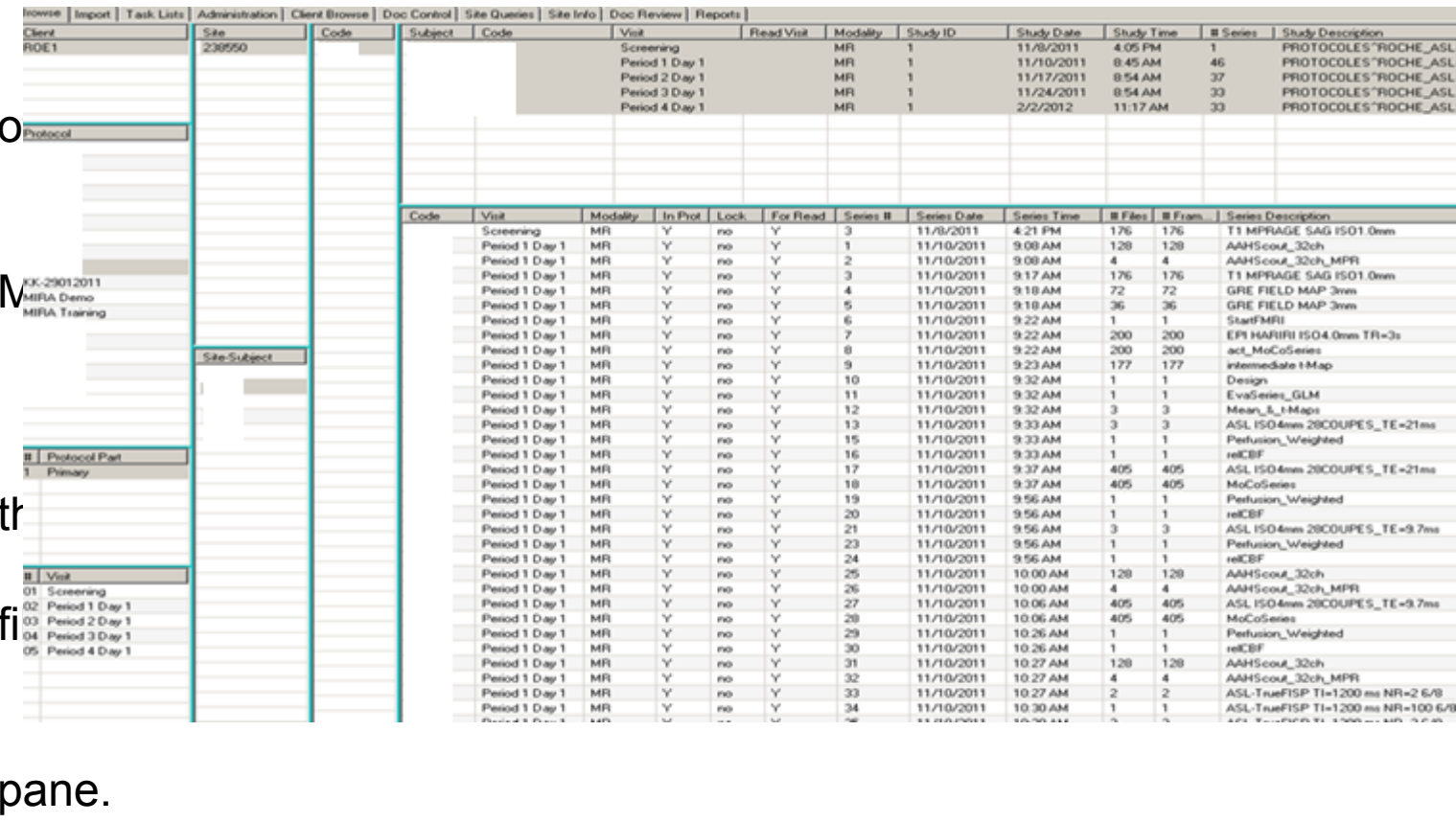


Figure 2: Listing

clinical images loaded into

Selecting a set of images allows the system to open

image DICOM

for review in the image viewing

pane.

MIRA™ is a validated system designed to service image data in DICOM format, which is the standard format for medical images. Images can be exported from the MIRA system and loaded back to MIRA™.

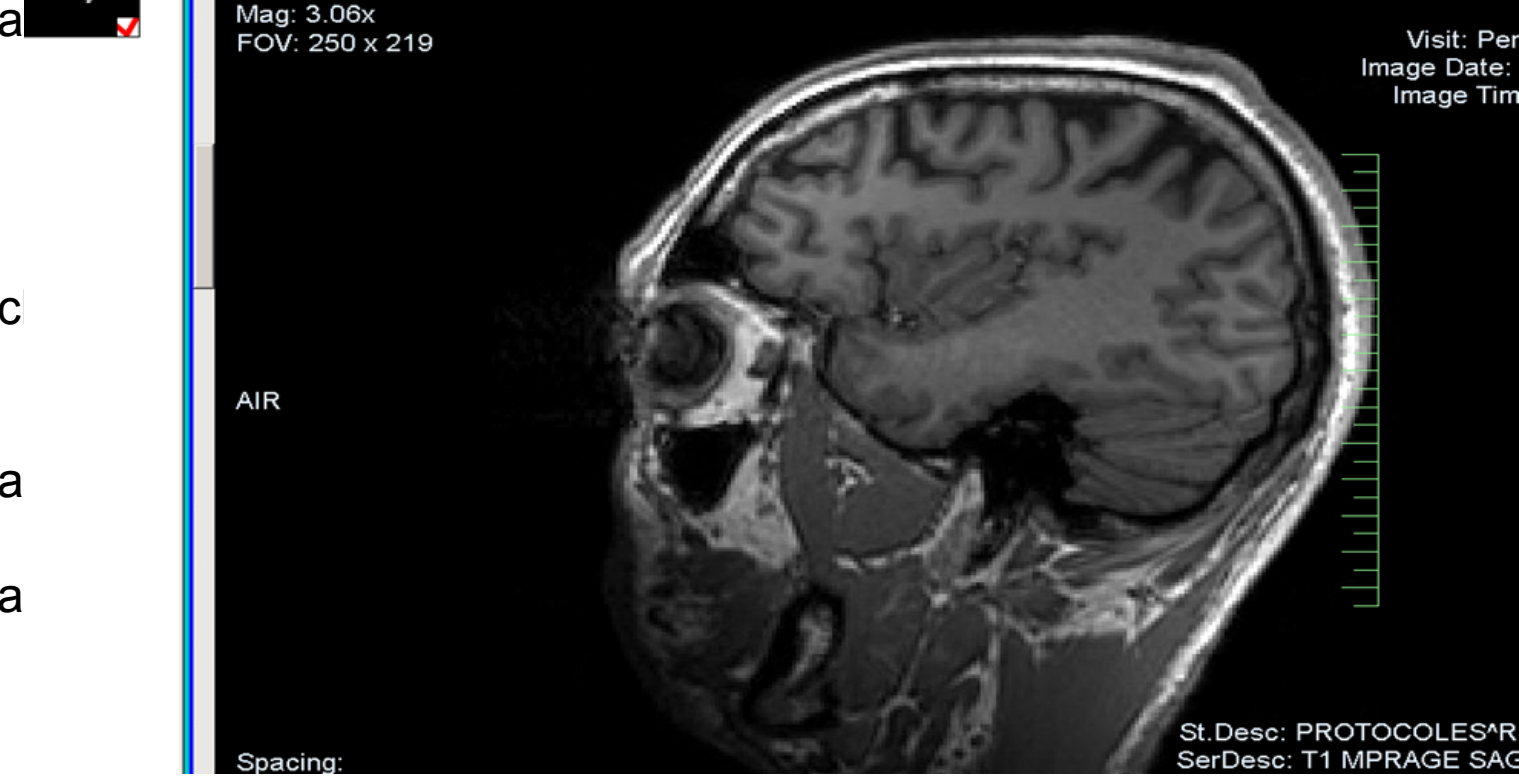


Figure 3: Clinical Images populated for review by

on a selection of specific images

demonstrated

4.BRINGING THE DATA TOGETHER

Using a specialized interface, we can directly link into the MIRA™ system which allows us to quickly review selected medical images relating to specific subject numeric data being reviewed within Spotfire®. The end result provides ideal, quick comparisons between numeric and image data allowing a greater, more accurate and more efficient integrated data review.

The interface template contains detailed instructions of steps to follow to select the subject specific images of interest required to be reviewed. By simply clicking on the highlighted selection in the *Images Available in MIRA™* table in Spotfire®, it automatically switches to the MIRA™ software to display the selected image/s of interest.

Figure 4: The Spotfire® to MIRA™ interface template.

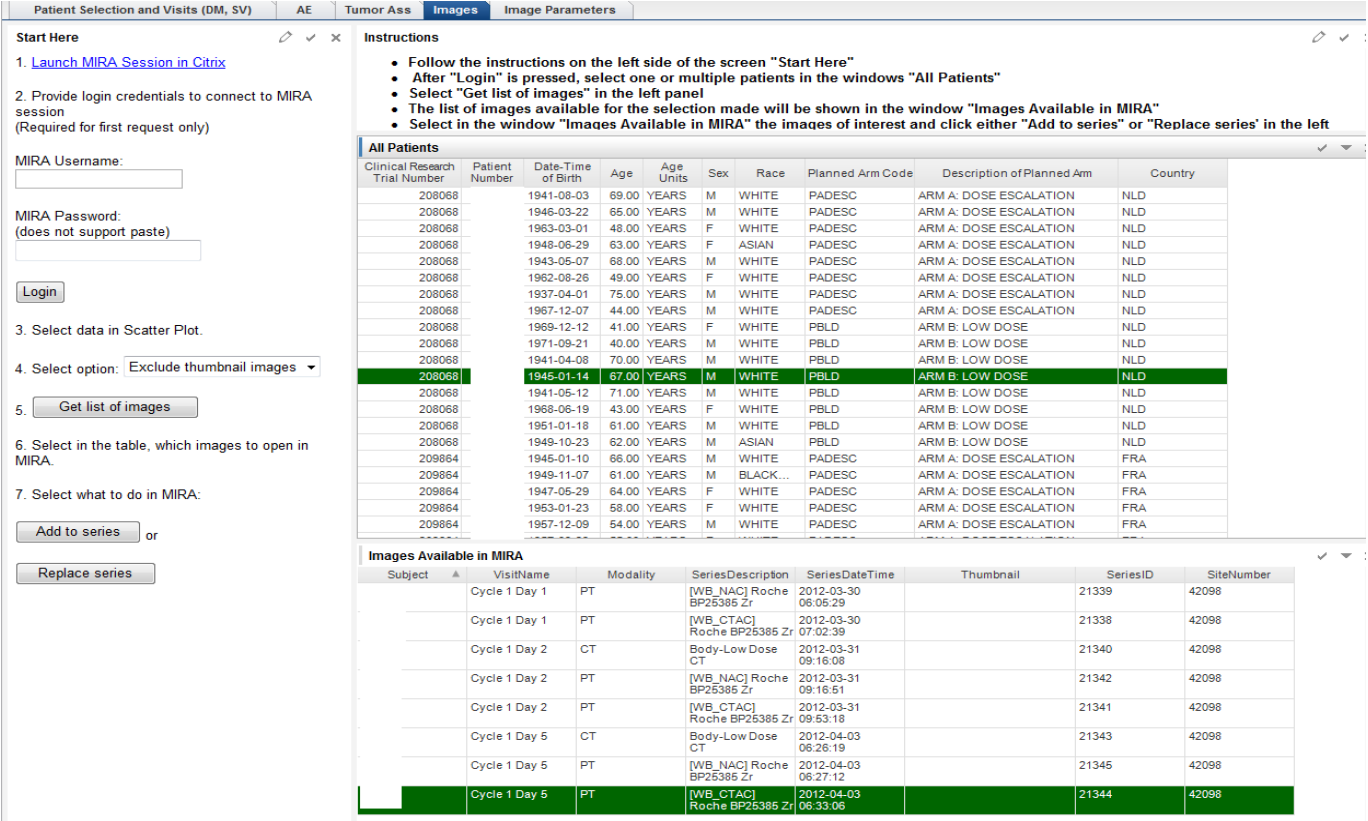
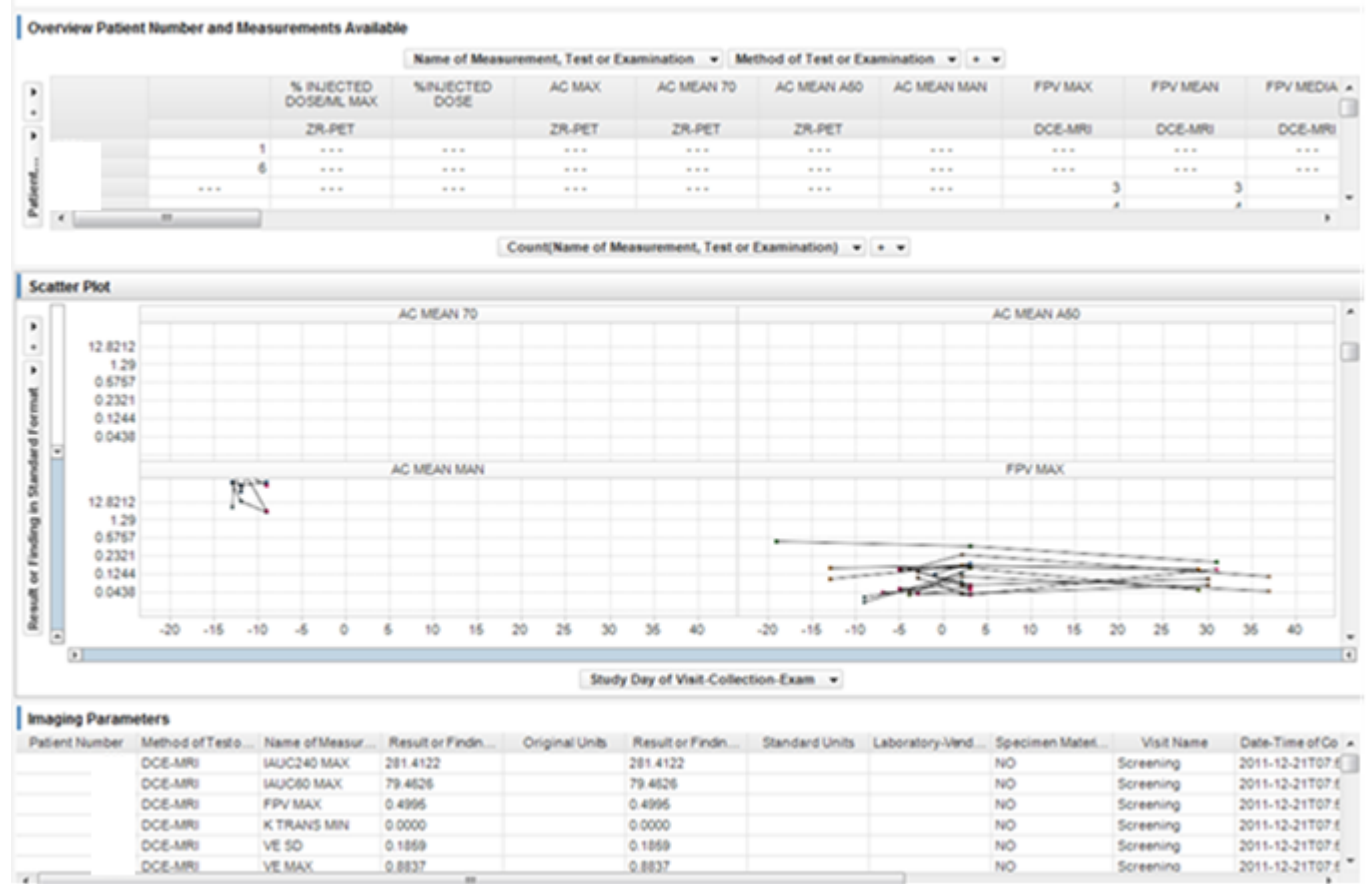


Figure 5: The specific images of interest displayed within MIRA™ as selected via the Spotfire® interface.



Numeric analysis measurements based on the clinical images as read by the imaging vendors can be uploaded to Spotfire®. Because of our Spotfire®/MIRA™ interface, our internal pRED Translational Imaging team is more optimally able to analyse the medical images first hand, allowing the review and comparison against the vendor provided numerical analysis, ensuring the most accurate and valuable data for the study.

Figure 6: Specialised data generated by image analysis can be reviewed and compared in Spotfire® between internal and external imaging experts for optimum data quality.



5.CONCLUSION

Clinical and imaging scientists have a wide range of tools available for evaluating different types of data during study conduct; however until now this consisted of reviewing different data types in different systems, which is not efficient or convenient. The images not being stored in the same database as the clinical other data captured in a study creates another hurdle: an integrated review of images and clinical data required to work with two systems in parallel: MIRA™ and RAVE™.

We at pRED have created a powerful data visualization interface allowing quick, accurate and high quality data evaluation, incorporating eCRF, numerical, electronic and graphical data with the medical images to provide optimum data value for each study.

