Standardization Mechanisms to Ensure High Quality Imaging in Clinical Trials

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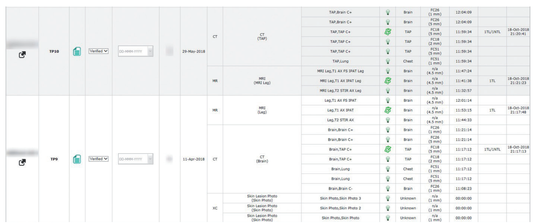
BACKGROUND

- Data quality derived from imaging within clinical trials can be suboptimal.
- The complex qualification pathway of imaging biomarkers and response criteria makes their performances not fully known.
- Lack of standardization of image acquisition across multivendor platforms.
- Ignorance of these pitfalls directly affects the quality of the imaging read-out, particularly when imaging is a primary endpoint. [1]

OBJECTIVES

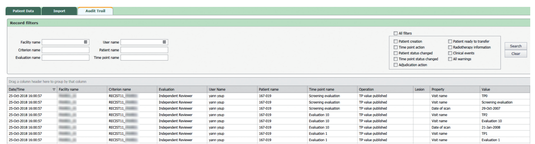
- Document the main cause for deviations or errors.
- Showcase some Quality Control systems.
- Suggestion of additional Quality Control improvements.

DATA SELECTION



Radiologists are responsable for a comprehensive review of the images dataset.
How to optimize?

→ **Image Ranking**



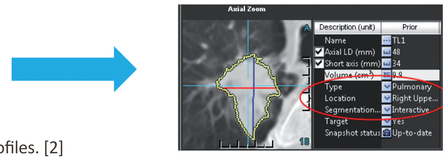
An automatic Quality Control

→ **Audit trail**

IMAGE ASSESMENTS

1. Compliance to standard

Automatic check and tracking of the optimal assessment method with respect to targeted diseases.

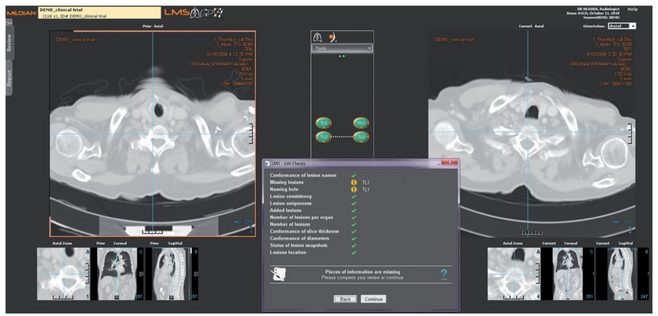


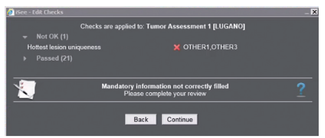
Standardized procedure:
The Quantitative Imaging Biomarker Alliance profiles. [2]

Benchmarking the reliability of imaging biomarkers through open non competitive challenges. [3]

Quantitative Imaging Biomarkers Alliance — RSNA

2. Response assessment





Complex criteria need software for response evaluation:

> Target Lesion
> Non-target
> New lesions
> Liver and spleen involvement
> Bonne marrow involvement

ELECTRONIC REPORTING

List of non-conformities	Ocurrence	Rate fo occurrence
Empty file	22	13%
None of the pages have been signed	19	11%
Calculation of % change of the tumoral burden not provided. Not documented	17	10%
New lesion not reported into the file	15	9%
No evaluation at all	13	8%
date of patients visit documented by clinical assistant: Missing date/Wrong Data	11	7%
No slice number (image) documented for lesions No number of the series documented	9	5%
Date of radiologist signature missing	9	5%
Comments or non expected data written on the file. Non-conformity as it cannot considered as a source document	9	5%
Radiologist's first name and given name not documented	8	5%
error in calculating the % of change, response is wrong	8	5%
Sum has not be calculated	5	3%
Non RECIST target has been selected	4	2%
Switch between target lesion - no impact on tumor burden	4	2%
Document rempli au crayon	3	2%
Both Target and non-target lesion have not be documented	2	1%
Wrong time point has been selected as Nadir	2	1%
Eroneous sum. Target lesions are correct but sum is wrong	2	1%
Page where target lesion are documented has not been signed	2	1%
Missing CRF or incoherent CRF	2	1%
No target lesion documented	1	1%
Obsolete file version was provided to radiologist	1	1%
TOTAL	168	100%

Non-conformity rates found in the Case Report Form (CRF):
55% with Paper form 5% when using eCRF [4]

CONCLUSIONS

- ✓ Standardized processes are key.
- ✓ Quality Control at each step of the process is required.
- ✓ Software is the key player enabling Quality Control.
- ✓ Structured reporting is of the utmost importance.

REFERENCES

[1] Liu Y. et al. A risk management approach for imaging biomarker-driven clinical trials in oncology, Lancet Oncol. 2015 Dec;16(16).
[2] Buckler et al. A collaborative enterprise for multi-stakeholder participation in the advancement of quantitative imaging. Radiology. 2011 Mar;258(3):906-14.
[3] Buckler et al. Inter-Method Performance Study of Tumor Volumetry Assessment on Computed Tomography Test-Retest Data. Acad Radiol. 2015 Nov;22(11):1393-408.
[4] Beaumont et al. Can we improve cost effectiveness of oncology clinical trials workflow? A prospective RECIST 1.1 study, ESMO Asia 2018.

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