Can we improve cost effectiveness of oncology clinical trials workflow?

A prospective RECIST 1.1 study

Hubert Beaumont [1], Antoine Iannessi [2], Catherine Klifa [1], Sebastien Patriti [2]

Median Technologies, Valbonne, France [1]; Centre Antoine Lacassagne, Nice, France [2]

BACKGROUND

Radiologists represent between 50% and 60% of the staff cost in clinical trials [1]. In the same time, radiological evaluations can be complex and time consuming.

For radiologists, clinical trials represent an additional workload with regard to their everyday duty which is primarily balanced among patient visits and a significant burden of administrative tasks.

Now, radiologist workload reach an unmanageable level and recurring non conformity issues are commonly reported. [2] [3]

OBJECTIVES

We compared the performance of an institutional standard radiological workflow (SW) with respect to a novel "hybrid workflow" (HWF) in terms of:

1. Number and nature of non-conformities
2. Radiologist reading time

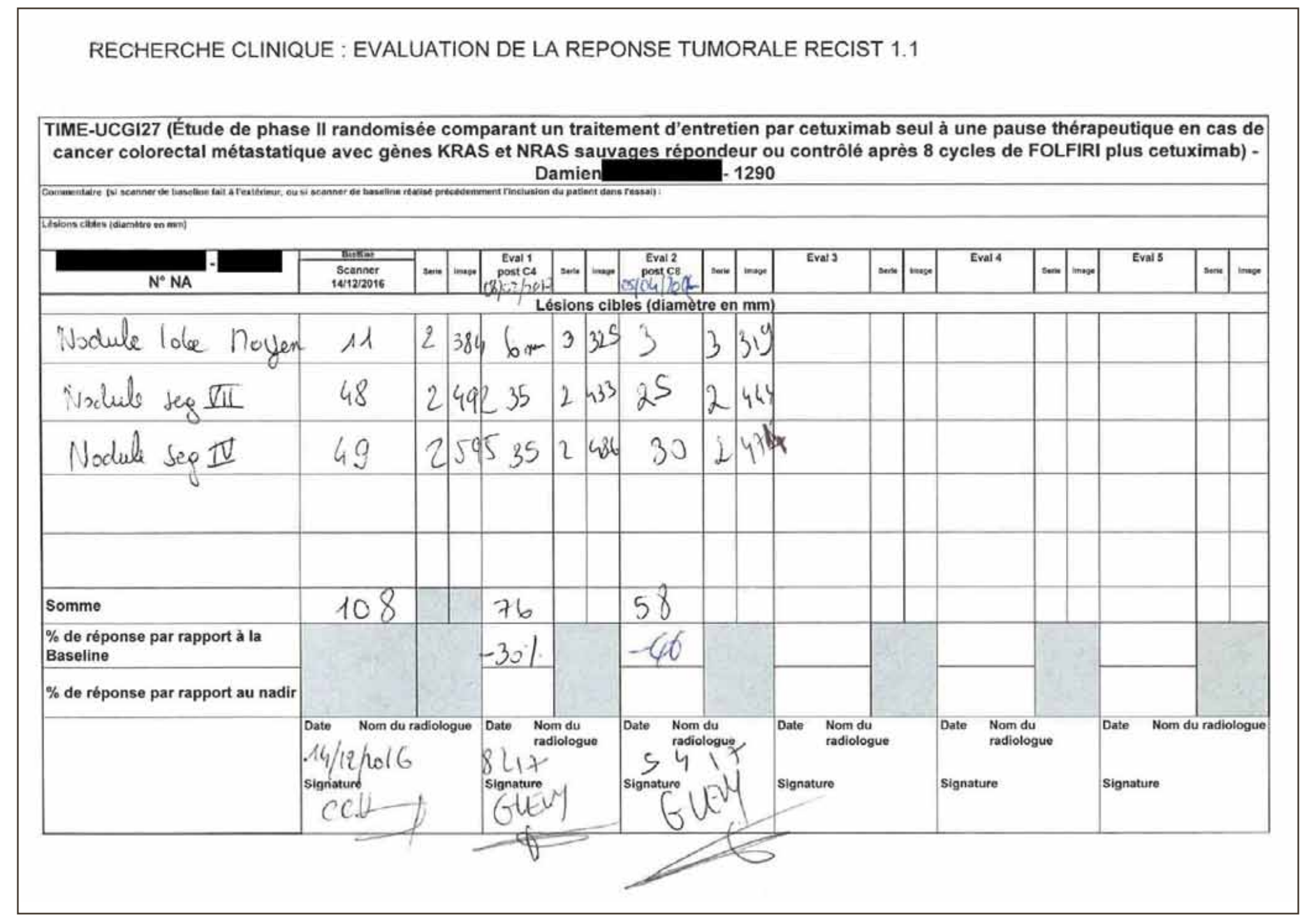
MATERIAL

We prospectively studied imaging data of 40 patients included in a RECIST 1.1 clinical trial (Apr-Dec, 2017) at Centre Antoine Lacassagne (CAL), Nice, France.

97 time-points were reviewed by 7 radiologists and one trained technologist.

Non conformities using the SW were retrieved from CALs' 2015 archives.

SW involved radiologists who used the Advantage Workstation platform **without electronic reporting system** (General Electric, USA).



RECHERCHE CLINIQUE : EVALUATION DE LA REPONSE TUMORALE RECIST 1.1

TIME-UCGI27 (Étude de phase II randomisée comparant un traitement d'entretien par cetuximab seul à une pause thérapeutique en cas de cancer colorectal métastatique avec gènes KRAS et NRAS sauvages répondeur ou contrôlé après 8 cycles de FOLFIRI plus cetuximab) - Damien [redacted] - 1290

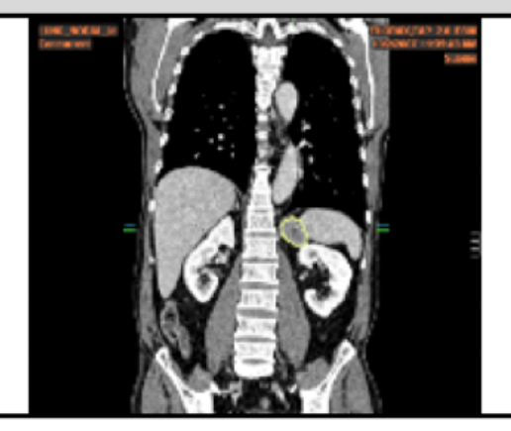
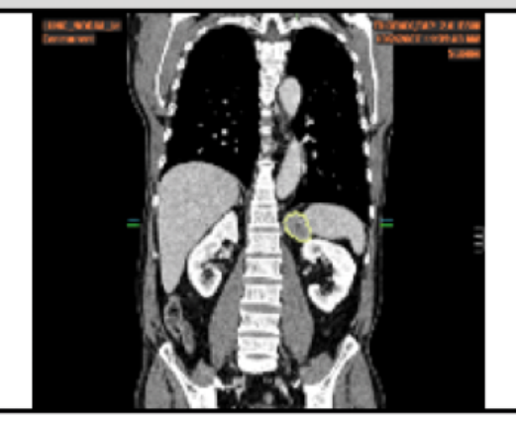
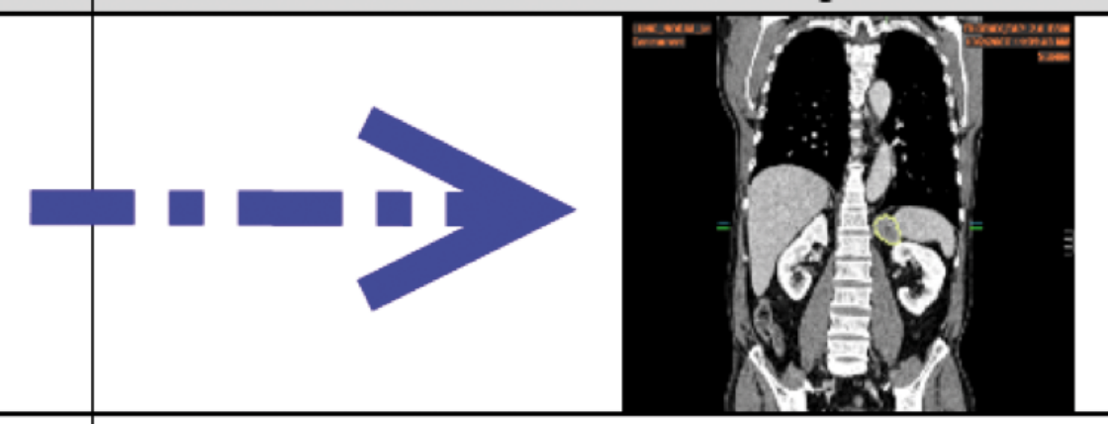
Commentaire (si scanner de baseline fait à l'extérieur, ou si scanner de baseline réalisé précédemment l'inclusion du patient dans l'essai) :

Lésions cibles (diamètre en mm)

[redacted] - [redacted] N° NA	Baseline Scanner 14/12/2016	Serie	Image	Eval 1 post C4 08/02/2017	Serie	Image	Eval 2 post C8 05/04/2017	Serie	Image	Eval 3	Serie	Image	Eval 4	Serie	Image	Eval 5	Serie	Image
Lésions cibles (diamètre en mm)																		
Nodule lobe Moyen	11	2	384	6mm	3	325	3	3	319									
Nodule seg VII	48	2	492	35	2	433	25	2	444									
Nodule seg IV	49	2	595	35	2	486	30	2	47[illegible]									
Somme	108			76			58											
% de réponse par rapport à la Baseline				-30%			-46											
% de réponse par rapport au nadir																		
	Date Nom du radiologue 14/12/2016 Signature			Date Nom du radiologue 8 2 17 Signature			Date Nom du radiologue 5 4 17 Signature			Date Nom du radiologue Signature			Date Nom du radiologue Signature			Date Nom du radiologue Signature		

METHODS

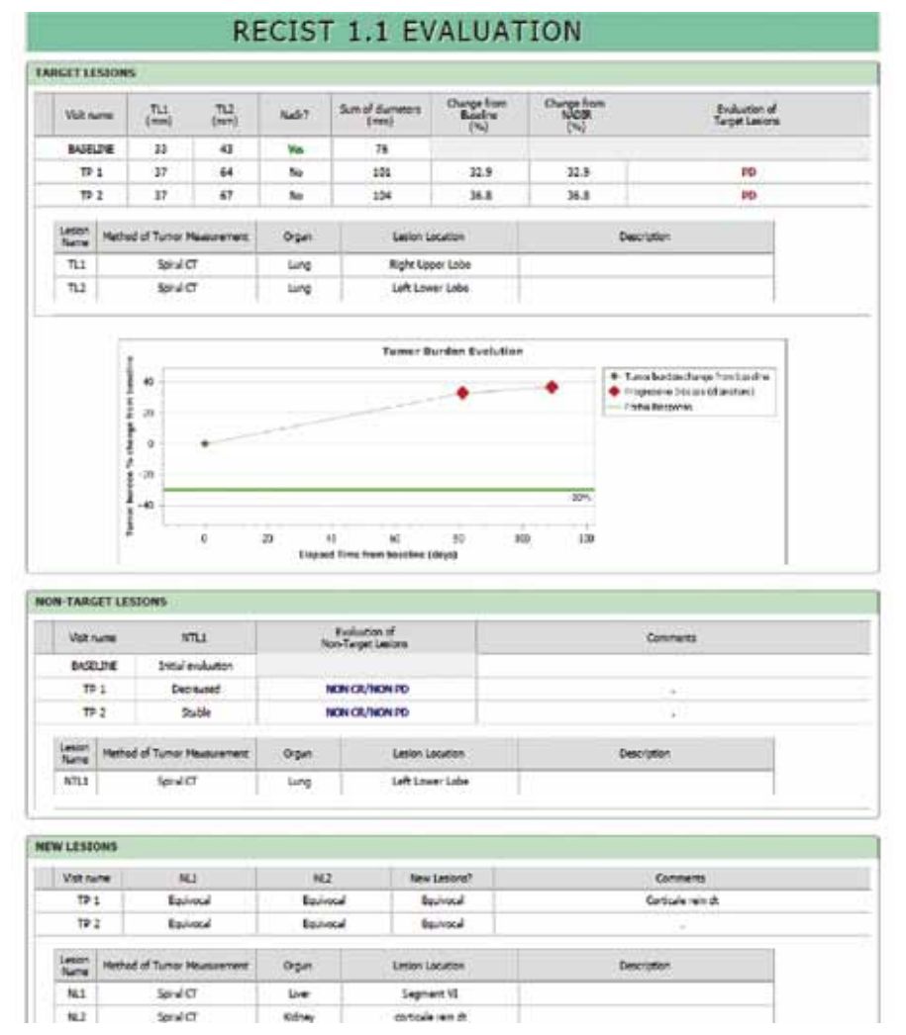
1. The hybrid workflow

Visits	Baseline	Time point 1	Time point N
			
Readers' Qualification	Radiologist	Technologist	Technologist
Readers' Confirmation	No	Radiologist	Radiologist

For the HWF (Above Figure), radiologists performed all baseline evaluations and the technologist did the subsequent generic measures on follow ups.

Radiologists then checked the technologist's findings, before confirming the evaluations.

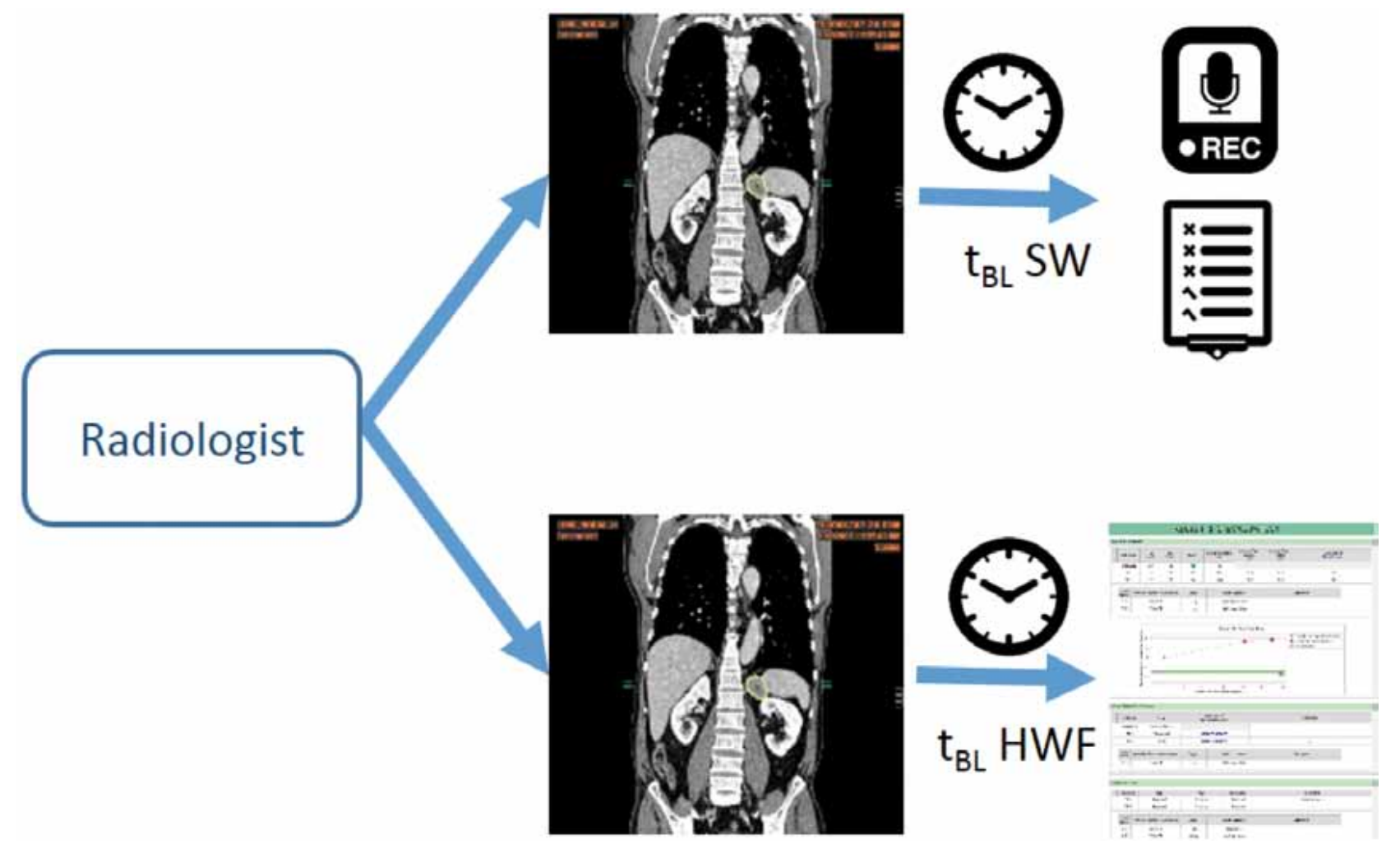
The HWF used LMS (Median Technologies, France) featuring an electronic reporting system (Right Figure).



RECIST 1.1 EVALUATION

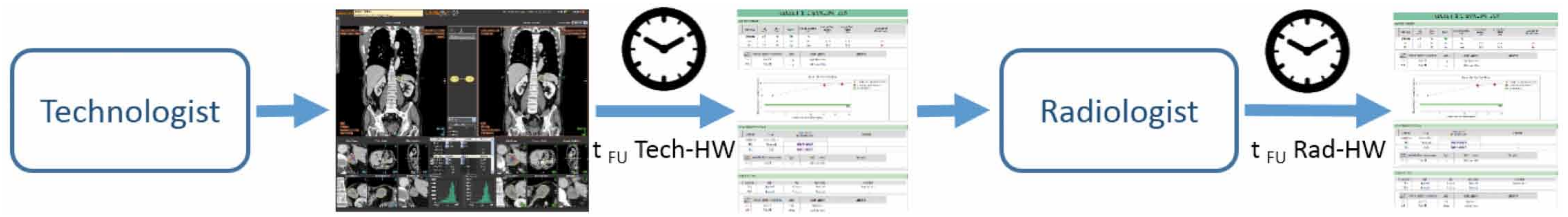
2. Our study design

Our study design allowed to perform two comparisons:



1) Duration of evaluations: left for baseline, below for follow up.

2) The comparison of non-conformities between the two workflows: check of all eCRF produced by HWF by an independent third party, results were compared to previous years rate of non-conformities reported in clinical trials at CAL.



RESULTS

Non Conformities	Ratio (%)
Blank report	13%
Unsigned report	11%
Undocumented change of tumor burden	10%
Undocumented new lesions	9%
Missing/wrong patients' visit date	7%
Undocumented tumors location	5%
Error in tumor burden change	5%

SW and HWF non conformities affected 55% (179/323) and 5% (2/40) of reports respectively ($p<0.001$).

HWF non conformities were: one wrong login name entered in the LMS platform and one erroneous time point numbering.

SW required, on average, 11'30" [10'06"; 13'20"] to perform the radiological analysis per timepoint. HWF required 1'35" [40"; 5'08"] for radiologists, and 12'18" [11'12"; 14'18"] for the technologist.

CONCLUSIONS

HWF reduced the number of trial non conformities and saved 87% of radiologists' time. HWF is an efficient cost reduction opportunity associated with quality improvements.

REFERENCES

[1] https://www.clinicalleader.com/doc/the-evolution-of-medical-imaging-in-clinical-research-0001

[2] F.H. Chokshi, et al. Diagnostic Radiology Resident and Fellow Workloads: A 12-Year Longitudinal Trend Analysis Using National Medicare Aggregate Claims Data, J. Am. Coll. Radiol. 12 (2015)

[3] S. Rohatgi et al., After-Hours Radiology: Challenges and Strategies for the Radiologist, Am. J. Roentgenol. 205 (2015)

ACKNOWLEDGEMENTS

We like to warmly thank Meriem Ketrandji, Jerome Mazoyer and Frederic Juste for their constant support in this project.

ESMO Asia 2018 | November 19-23, 2018 | Singapore | Abstract No 548P

Contact: hubert.beaumont@mediantechnologies.com

There is no conflict of interest