



Local (Site) Clinical Trial Reads and Centralized Clinical Trial Reads

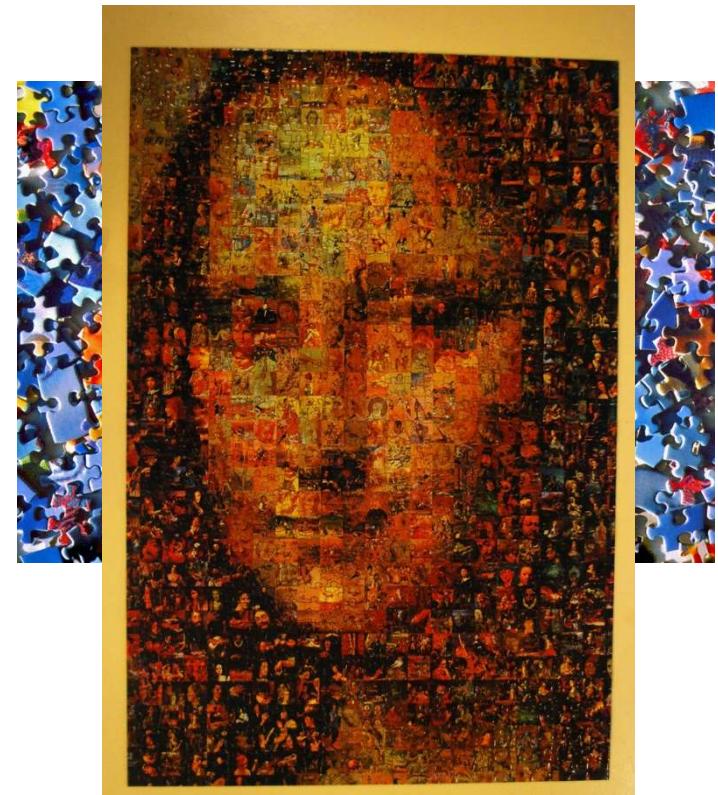
A look at underlying causes of perceived discordance
(and why it may not be what we thought)

Mint Medical
Kelie H Luby, VP Clinical Trials

Developed in
cooperation with
dkfz.
DEUTSCHES
KREBSFORSCHUNGZENTRUM

Why speak on this topic?

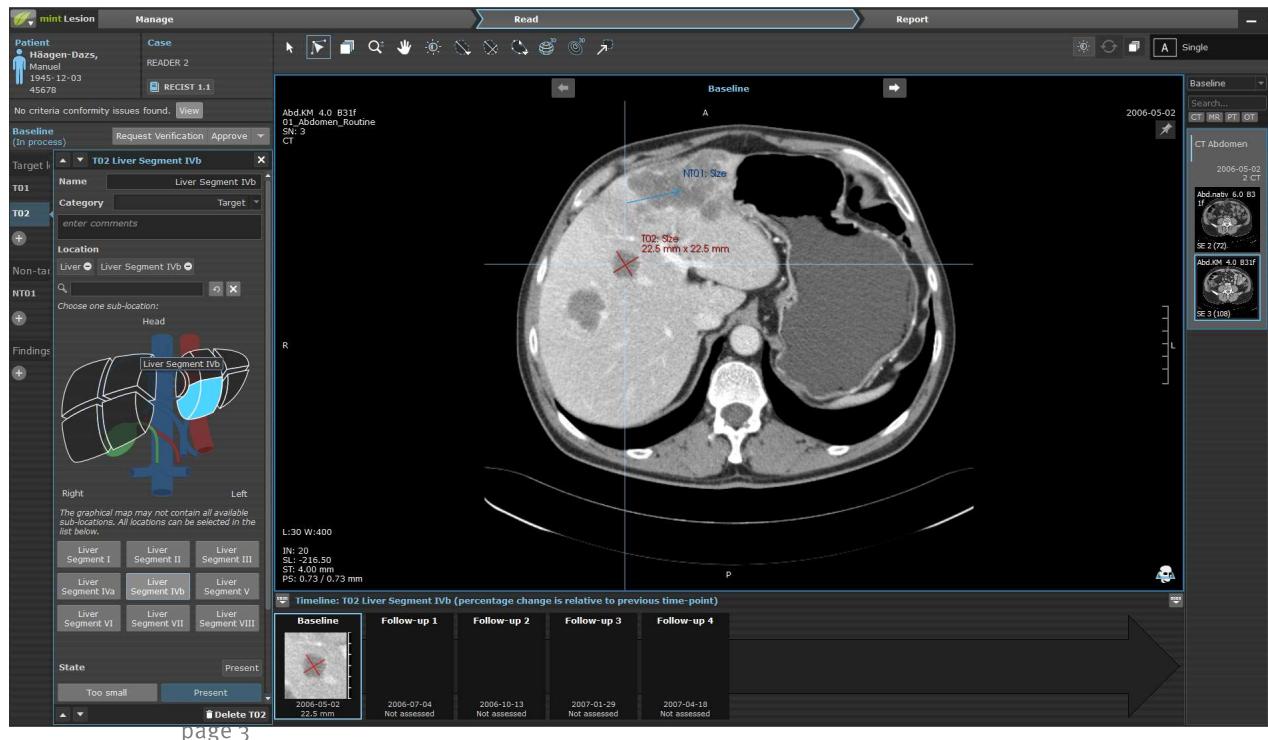
- Still relevant
- Many efforts to ‘minimize’/‘control’ discordance
 - Site and central select same target lesions
 - Site and central adjudication
- Larger Question:
 - Is it solvable and should we solve it?
 - What does solving it mean?
- Many avenues to explore
- Today’s avenue....
 - Workflow, Workflow, Workflow
 - Reporting
 - Consumers
 - Training
 - Economics



Background

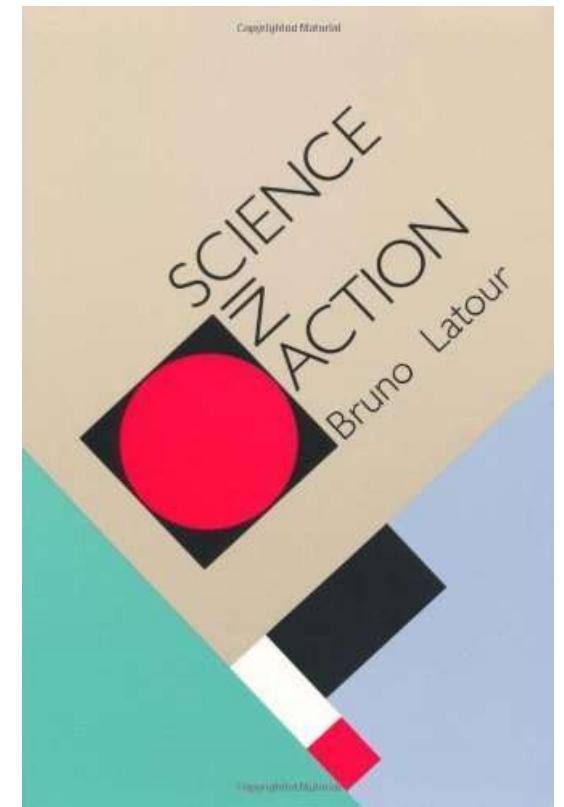
- Medicinal Chemist (part 1)
- Scientific and Medical Communication (part 2)
- 10 years at Perceptive/ PAREXEL
- 2 years at Imaging Endpoints

2016.....Mint Medical
Work with many CROs, Academic and Cancer Centers



A philosophical look at data

- Bruno Latour – Immutable Mobiles
 - Science in Action: How to follow scientist and engineers through society (1987)
- Describes how information is passed from between ‘agents’
 - Newspaper, Scientific Publication, Response Criteria, Radiology Report
 - Premise: Easily transported between agents (people/institutions) and has permanence
- Importance:
 - Allows coalition building around an idea
 - Proof (map)
 - More important – comparable
 - The act of making an concept permanent through creating a ‘immutable mobile’ does not mean that EXACT information exists
 - Unification around an idea.



Site and Central: What is the difference?

Clinical Site Reads (Academic/ Cancer Centers)

- These are the hospital and Cancer Centers where the patient is treated
- PI (ex. Oncologist) oversees response evaluation read
- May have a specific Radiology Response Assessment form (tumor form or RECIST form) or PI extracts information from clinical report
- Oncologist may perform their own tumor measurements
- Oncologist and radiologist may interact to determine final response for patient
- A clinical trial can have 100's of sites and investigators
 - An academic center/cancer center is one site
- PI/Oncologist treats the patient

Central Reads (Imaging Core Lab/ Imaging CRO)

- These are dedicated groups/companies that DO NOT treat the patient
- Interact with Pharma/Biotech and Sites to obtain the images
- Train readers and standardize the response evaluation to minimize variability
- High quality data records
- Small group of trained readers with expertise in response criteria doing a pure review of the imaging data in accordance with standardized criteria in a highly controlled fashion
- Core Lab Radiologist are NOT treating the patient:
 - Not influenced by the patient's personal history/current health
 - Not influenced by investigator

Central Review = Better

Central Review

- Better application of assessment criteria
- Radiologists, etc. are better trained on criteria and how to review images in clinical trials
- Radiologists select and follow the disease burden more carefully
- Fewer radiologist readers leads to less variability in reads
- The same radiologist usually reviews the case for a given subject
- Better quality control and monitoring at CROs
- Not influenced by patient/ PI – No Bias; Blinded



Workflow and Operational Processes

Workflow and Operational Process – Centralized Review- Part 1

- Primary Decision Maker
 - CRO
- End User
 - Sponsor – Pharma/Biotech
- Images
 - Sent to CRO from clinical sites
 - Missing imaging is common and challenging to track
 - Find what you don't know you are missing
- Notifications
 - Radiologist notified by CRO when to perform reads
- Reporting and Tracking Tools
 - Dedicated software to track measurements and assessments
 - Edit Checks to prevent errors
- Training
 - Formal and in depth protocol related training
 - Testing cases
 - Reader Qualification

Workflow and Operational Process – Centralized Review-Part 2

- Roles
 - Well defined
 - Project Managers
 - Scientific and Medical Oversight
 - Radiologists and physician specialist readers
 - Data Management
 - Regulatory and Quality Oversight
- Data Management
 - Dedicated teams
 - Well-controlled oversight of data / Universal/ reproducible
- Quality Control
 - Large investment in assuring/maintaining data integrity and adherence to GCP
- Economics (Time and Money)
 - Project Planning -major aspect of the oversight
 - Cost are typically well known and planned
 - Reads are billable (part of contract related fees or at cost)

Workflow and Operational Process - Clinical Site- Part 1

- Primary Decision Maker
 - Primary Investigator
- End User
 - Patient
- Images
 - Local patient images
 - Images from outside institutions
 - Patients may be on multiple clinical trials
 - Determine where one clinical trial ends and one begins
 - All patient images in an institution may be accessible
 - Which images are applicable (Is that arm x-ray or that shoulder MRI really applicable to the RECIST read?)
 - Routine reads and clinical research reads
 - Sometimes performed by same person; sometimes different radiologists
 - Is the routine read provided during the clinical research read?
 - Which ‘read’ takes priority in the patient response to treatment if discordant?
 - Routine says stable but RECIST says PD – Does the patient stay on trial?

Workflow and Operational Process - Clinical Site – Part 2

- Reporting and Tracking Tools
 - Sites may have tumor tracking forms
 - RECIST forms
 - Lack of linkage with viewer and measurement tools
 - Homegrown tracking software
 - Directly measure in PACS
 - Oncologist takes measurements from routine radiology report or PACS to do clinical trial assessments
 - Often no ‘version control’ or tracking over time
 - How do you find the nadir?
- Notifications
 - How does the radiologist doing clinical research reads get notified?
 - How does the radiologist know which criteria to use?
 - What about particular modifications to the protocol?

Workflow and Operational Process - Clinical Site – Part 3

- Measurements
 - Often no structured or standardized procedure for seemingly routine factors
 - Lesion Locations
 - Use of measurement tools
 - ‘eyeballing’ right axis
 - Reporting only one axis (wrong axis) without labeling - may be transposed/inferred to be short axis
 - Measuring too many lesions
 - Measuring wrong lesion at follow up due to disharmonized systems
- Training
 - Formal criteria training is a rarity; typically through conferences or On-the-Job
 - No per ‘Protocol’ training

Workflow and Operational Process - Clinical Site – Part 4

- Study Personnel
 - Research Teams vary:
 - From small teams of 2-3 people doing all research reads (Technologist + Radiologist)
 - Moderate size teams with 1-3 primary radiologists with some additional support from other departments (Neuro, Nuclear medicine)
 - Large teams of 30-40 Radiologists and 100+ PIs and study coordinators with other support staff
 - Roles
 - Study coordinator
 - Study Nurse
 - Technician may do preliminary review and send to radiologist for approval
 - Junior radiologist with approving senior radiologist
 - Multiple radiologist reviewing the same case
 - PI (sometimes using routine radiology report to determine response assessment)

Workflow and Operational Process - Clinical Site – Part 5

- Data Management
 - Report Data for Pharma/Biotech into EDC (Medidata RAVE)
 - Reporting is still almost entirely manual data entry even at very large research centers
- Quality Control
 - Most often by virtue of the PI/Research coordinator contacting the radiologist
 - Evaluation is based on impact to patient care/potential patient harm
 - Measurements may often be easily manipulated or modified
 - If systems are not created by design for clinical research work – no HIPPA structure or validation
- Economics (Time and Money)
 - Money:
 - Sometimes clinical research reads are funded
 - Often times there is no ‘billing’ for research reads
 - Time:
 - Research reads done by dedicated groups with time slotted in department for reads
 - Reads done in evenings and off-time with no dedicated time to do the work

Assessment Criteria

RECIST 1.1

iRRC

iRECIST

iRECIST

RECIST 1.0

RANO

Macdonald

Choi

WHO

PCWG2/3

RECIL

mRECIST HCC

PERCIST

EORTC

Cheson 2007

TNM

LYRIC

iRANO

Brodeur

IWCLL

BI-RADS

LI-RADS

PI-RADS

Deauville

Milan

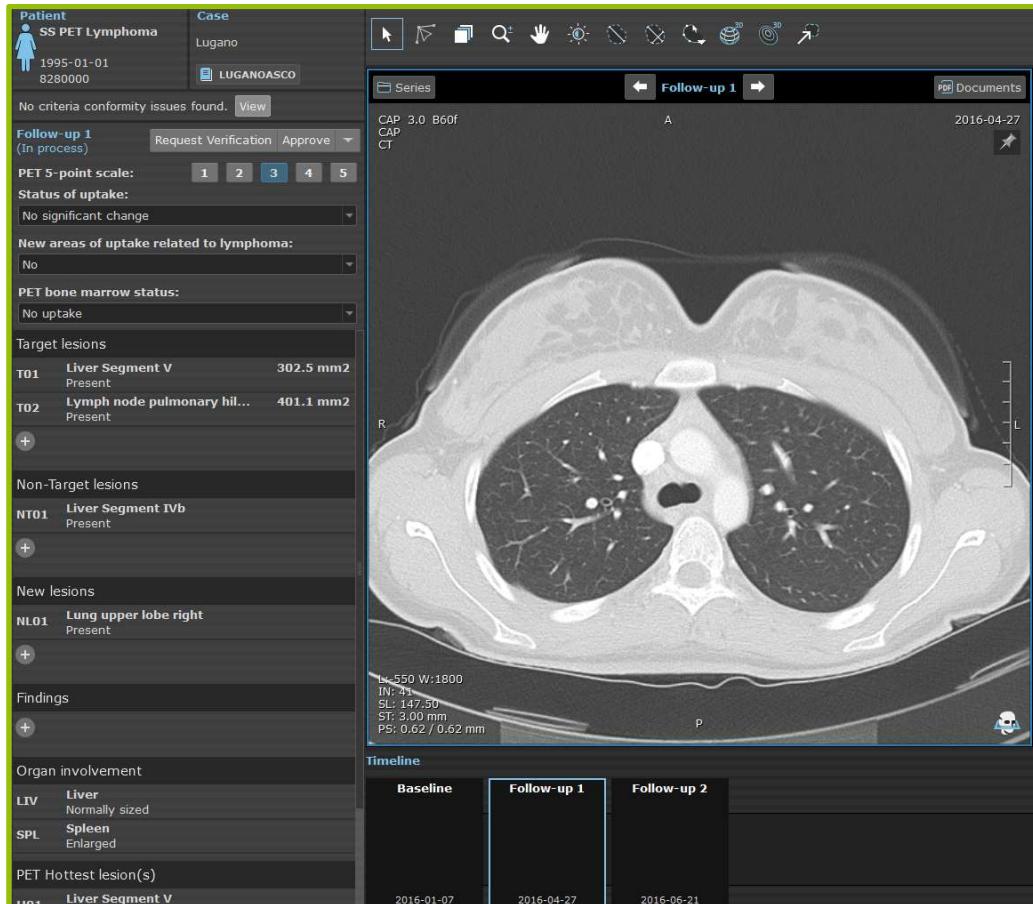
mRECIST Mesothelioma

Lugano (Cheson 2014)

Standardization with Variability

- What is the minimum lymph node size in:
 - RECIST 1.1
 - irRC
 - iRECIST
 - Lugano
 - Cheson
- Progression Thresholds?
 - RECIST 1.1
 - WHO
 - irRC
 - Lugano
 - RANO
 - Choi
 - LYRIC

Assessment Criteria are Complex



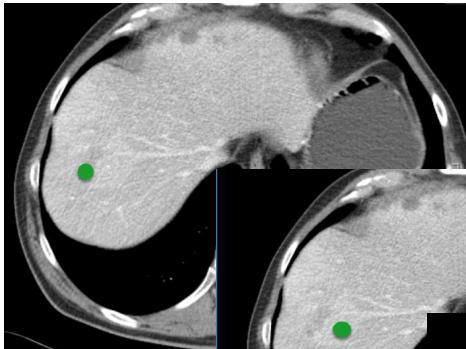
- CT Assessment
- PET metabolic Score
- SUV of hottest lesion
- SUV of all lesions
- Measurements of ALL nodes
- Deauville Score
- Change in Uptake
- Reference Tissue Evaluation
- Spleen Measurement
- Liver Evaluation
- Sum of Diameter Changes
- Calculations for Decrease from Baseline/Increase from Nadir

The Importance of Relevance

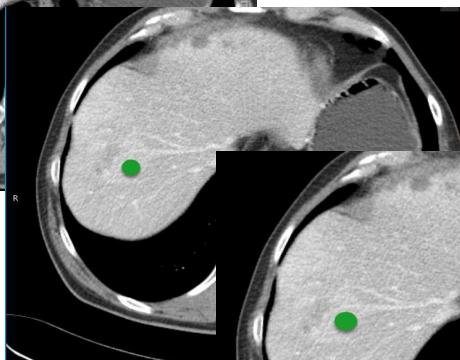
- Recall - Challenge at the Clinical Site:
 - Lack of linkage with viewer and measurement tools
 - Often no ‘version control’ or tracking over time
 - How do you find the nadir?

Is the patient progressing?

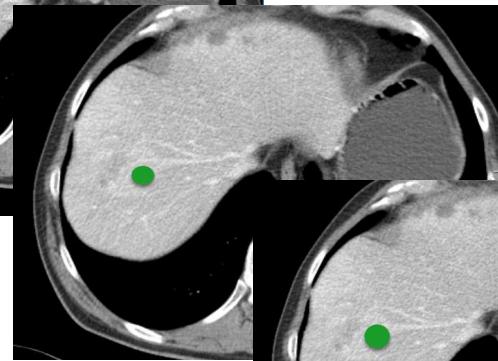
What is the time point of
Progression?



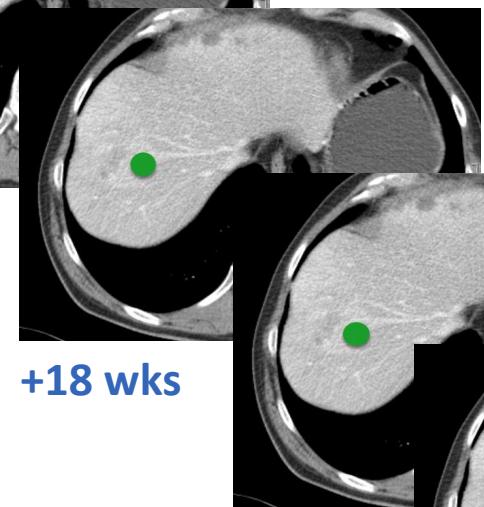
BL



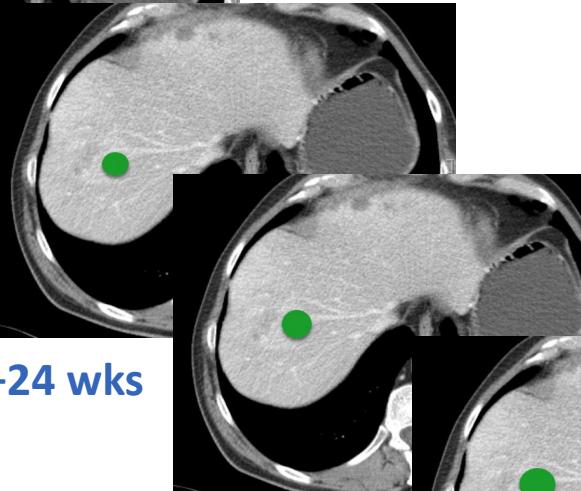
+6 wks



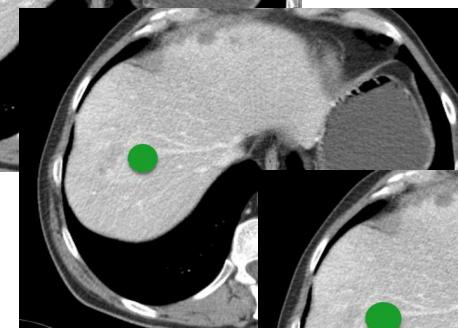
+12 wks



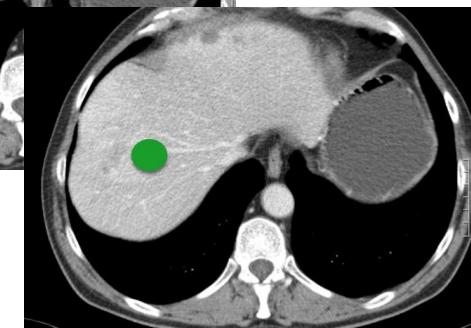
+18 wks



+24 wks



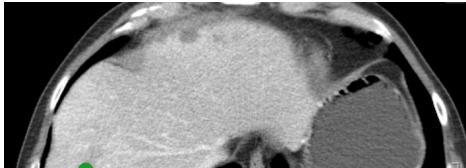
+48 wks



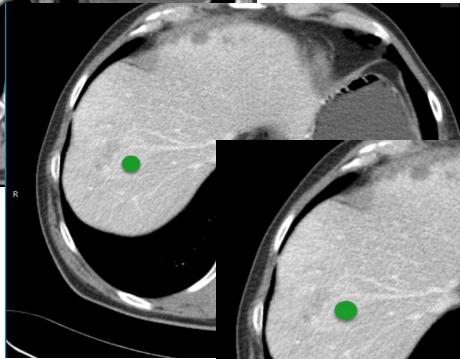
+72 wks

Is the patient progressing?

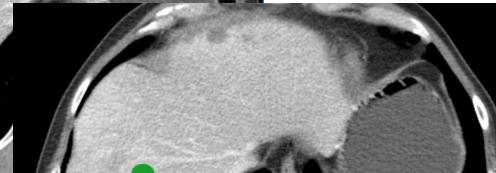
What is the time point of Progression?



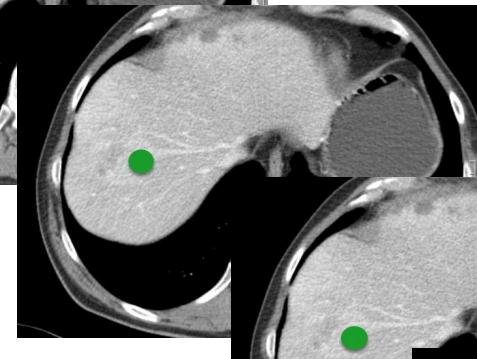
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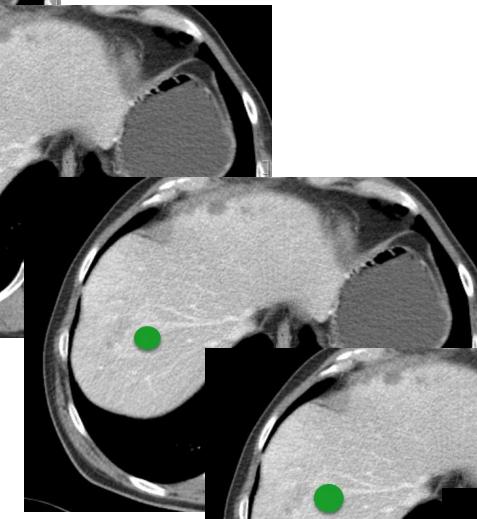
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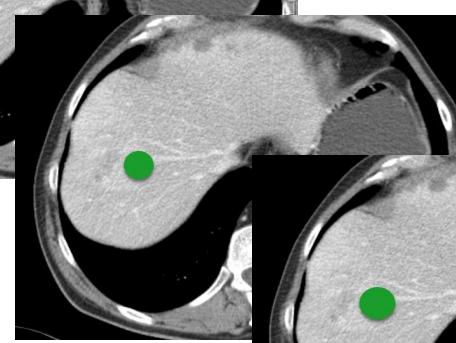
+12 wks



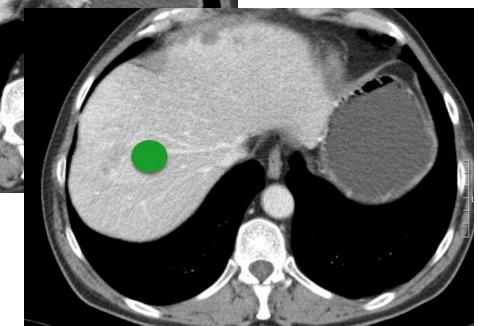
+18 wks



+24 wks



+48 wks



+72 wks

- Without the right tools, sites can miss slow progression – *Compare to previous exam instead of BL or Nadir*

What's Missing?

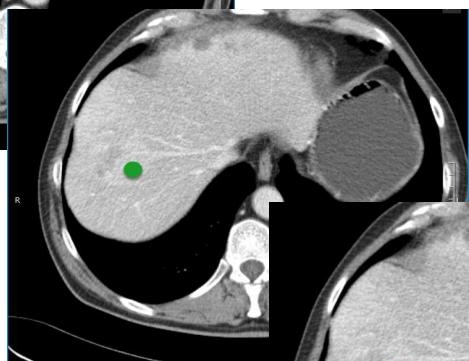
- Recall - Images
 - Clinical Site:
 - Local Patient Images
 - Images from outside institutions
 - Patients may be on multiple clinical trials
 - Determine where one clinical trial ends and one begins
 - All patient images in an institution may be accessible - Which images are applicable (Is that arm x-ray or that shoulder MRI really applicable to the RECIST read?)
 - Central Review
 - Sent to CRO from clinical sites
 - Missing imaging is common and challenging to track
 - Find what you don't know you are missing

Is the patient progressing?

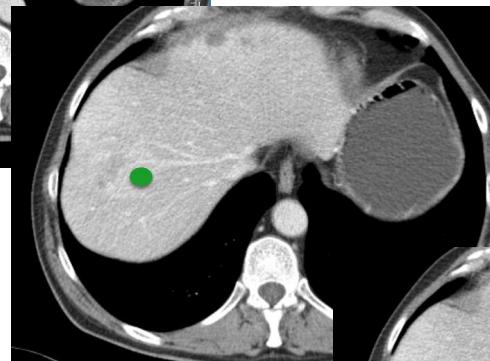
What is the time point of
Progression?



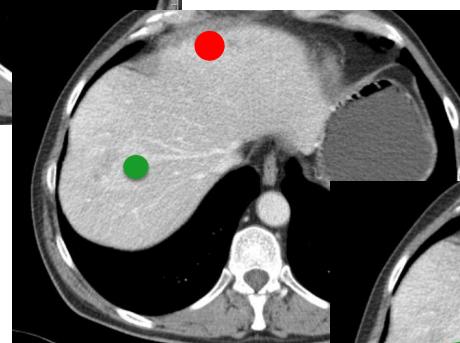
BL



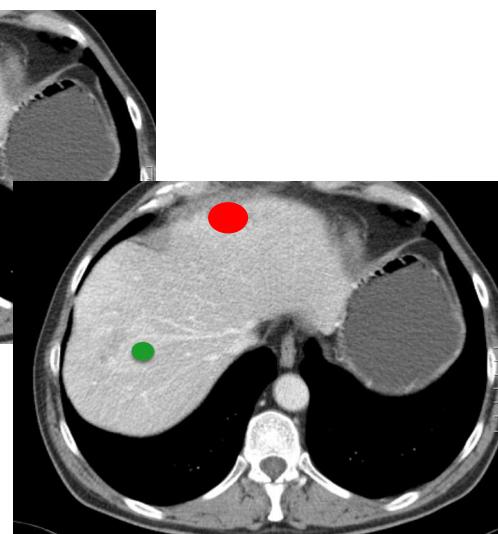
+6 wks



+12 wks



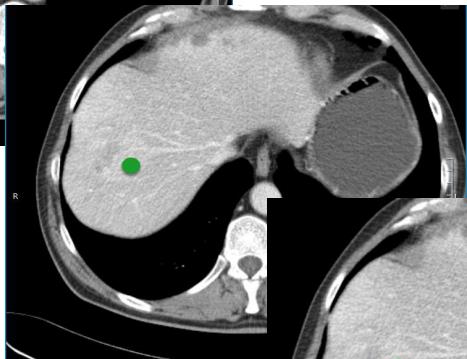
+18 wks



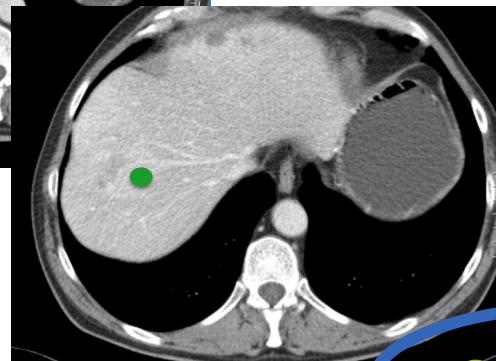
+24 wks



BL



+6 wks

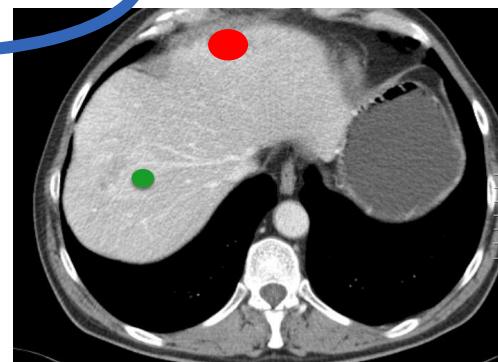


+12 wks

Is the patient progressing?

What is the time point of Progression?

???????



+24 wks

- Not all images at the site make it to the Core lab/CRO – this leads to discordance on Date of Progression
- Very common

Reporting

- Recall - Measurements
 - Clinical Site
 - Often no structured or standardized procedures
 - Lesion Locations
 - Use of tools
 - Reporting only one axis (wrong axis) without labeling - may be transposed/inferred to be short axis
 - Measuring too many lesions
 - Measuring wrong lesion at follow up due to disharmonized systems
 - Central Review
 - Dedicated software to track measurements and assessments

Tumor Tracking Form

UCLA **TIMG DIAGNOSTIC RADIOLOGY
RESEARCH IMAGING REQUEST FORM**

Patient Name: _____ DATE: _____
 DOB: _____ PRIMARY DIAGNOSIS: _____
 P.I.: _____ IRB#: _____
 SPONSOR/COMPANY: _____
 STUDY NAME: INDUSTRY SPONSORED TRIAL
 INVESTIGATOR INITIATED TRIAL
 REQUESTED BY: NAME: _____ FAX: _____ PHONE: _____
 TYPE OF PROCEDURE REQUESTED:
 (Also attach Physician's Order) _____
 ANATOMICAL AREA: Chest CONTRAST: Oral Contrast
 Abdomen IV Contrast
 Pelvis with/without contrast
 EVALUATE USING: WHO Criteria COMPARE TO: Previous Scan
 RECIST 1.0 Criteria None-Baseline Scan
 RECIST 1.1 Criteria
 Cheson/Halleck
 Other: _____
 CHARGE INSURANCE: Imaging & Reading CHARGE STUDY: Imaging & Reading
 Imaging only (Grant) Imaging only
 Reading only Reading only
 SPECIAL INSTRUCTIONS: _____
 Please fax a copy of the completed report to:
 Phone #: _____ Fax #: _____ E-Mail: _____
 Tower Saint John's Imaging
 2202 Wilshire Blvd.
 Santa Monica, CA 90403
 Phone 310-264-9000
 Fax 310-264-9004
<http://www.towersji.com>

TOWER IMAGING MEDICAL GROUP – RECIST 1.1 TUMOR TRACKING FORM

NAME/SUBJECT#	MR #		
PRINCIPAL INVESTIGATOR	SPONSOR/STUDY		
RESEARCH COORDINATOR	PHONE#:		
EVALUATION STANDARD(Circle):	RECIST 1.1	FAX #:	
RADIOLOGIST(Signature):			
ONCOLOGIST/PI (Signature):			
STUDY TYPE (Circle):	CT/MR H/N/C/A/P OTHER: _____	CT/IMR H/N/C/A/P OTHER: _____	CT/IMR H/N/C/A/P OTHER: _____
DATE:	DATE:	DATE:	
Body Parts: 1 2 3 4 5 6	Body Parts: 1 2 3 4 5 6	Body Parts: 1 2 3 4 5 6	

TARGET LESIONS

#_LESION DESCRIPTION	SIZE (mm)	(Image #)	SIZE (mm)	(Image #)	SIZE (mm)	(Image #)
1	()	()	()	()	()	()
2	()	()	()	()	()	()
3	()	()	()	()	()	()
4	()	()	()	()	()	()
5	()	()	()	()	()	()

NON-TARGET LESIONS

#_LESION DESCRIPTION	Present(+) / Absent(-)	Present(+) / Absent(-)	Present(+) / Absent(-)	
1	NonCR/NonPD	CR PD NE	NonCR/NonPD	CR PD NE
2	NonCR/NonPD	CR PD NE	NonCR/NonPD	CR PD NE
3	NonCR/NonPD	CR PD NE	NonCR/NonPD	CR PD NE
4	NonCR/NonPD	CR PD NE	NonCR/NonPD	CR PD NE
5	NonCR/NonPD	CR PD NE	NonCR/NonPD	CR PD NE

NEW LESIONS

#_LESION DESCRIPTION	Status	Status	Status
1	Yes No NE	Yes No NE	Yes No NE
2	Yes No NE	Yes No NE	Yes No NE
3	Yes No NE	Yes No NE	Yes No NE

Version 5.0 (last modified 11/6/12) Always fax to Cancer Clinical Trial Office and to Rafael Ramirez at 323-549-3062 Page: ____/____

Reference: Ira Smalberg, MD Tower Imaging Medical Group. PINTAD 2014 Presentation

Reporting

- Survey of Oncologists and Radiologists:
 - Most oncologists (75%) thought the target lesion selection and follow up should be in a joint session with radiologist + oncologist not as done with the current paradigm
 - Current: Oncologist select and measure target lesions on their own
 - 60% of oncologists still hand write measurements on tumor tracking forms or hand write measurements on scrap paper before transferring information to an electronic form
- Reference: Quantitative Radiology Reporting in Oncology: Survey of Oncologists and Radiologists. L. Folio et. al., AJR:205, September 2015.

REPORT CT scan of the chest WITH intravenous contrast, using standard protocol.

COMPARISON: CT chest 3/15/2013.

FINDINGS:

Lines/tubes: None.

Lungs and Airways: There has been a left upper lobectomy for lung cancer. There is right apical scarring there is a new ill-defined patchy groundglass opacity measuring 9 mm in the right upper lobe on image 51.

There are several nodules some of which are solid and some of which are groundglass opacity. In the right upper lobe on image 51 there is a 0.95 cm nodule which is mostly of groundglass opacity and is unchanged in size. There is also just inferior to with on image 53 a second 3 mm nodule which is also unchanged. There is a mixed groundglass solid nodule abutting the minor fissure on the right side also unchanged.

On the left side there is a nodular lesion which is solid with a tail to the pleura that is unchanged. There is also an area of what appears to be subpleural consolidation in the lingula which measures 1.9 x 2.9 cm as compared with 1.8 x 2.6 on the previous study. There is additional opacity in the lingula but may represent atelectasis.

Pleura: There is a small left pleural effusion that is unchanged.

Heart and mediastinum: The thyroid gland is normal. No significant mediastinal, hilar or axillary lymphadenopathy is seen. The heart and pericardial effusion

Soft tissue

Abdomen: abnormal kidneys.

Bones: Th suspicious

IMPRESSION
Status po

Multiple pulmonary nodules some which are solid and some of which are groundglass with little significant change since March 2013. However as compared with May 2012 the lingular opacification has definitely increased in size. There is also a new groundglass focal opacity measuring about a centimeter in the right upper lobe. The findings are concerning for recurrent adenocarcinoma.

Small pericardial effusion and small left pleural effusion unchanged

Multiple pulmonary nodules some which are solid and some of which are groundglass with little significant change since March 2013. However as compared with May 2012 the lingular opacification has definitely increased in size. There is also a new groundglass focal opacity measuring about a centimeter in the right upper lobe. The findings are concerning for recurrent adenocarcinoma.

Small pericardial effusion and small left pleural effusion unchanged

Radiology Report

Example: Lung Cancer

Word Choice

- ‘Indeterminate lymph nodes’
- ‘Inconclusive for progression’
- The phrase ‘cannot be excluded’
- ‘Need additional time point’
- ‘Possible infection’
- ‘Concerning’
- ‘Likely progression’
- ‘May represent a new lesion”

Multiple pulmonary nodules some which are solid and some of which are groundglass with little significant change since March 2013. However as compared with May 2012 the lingular opacification has definitely increased in size. There is also a new groundglass focal opacity measuring about a centimeter in the right upper lobe. The findings are concerning for recurrent adenocarcinoma.

Small pericardial effusion and small left pleural effusion unchanged

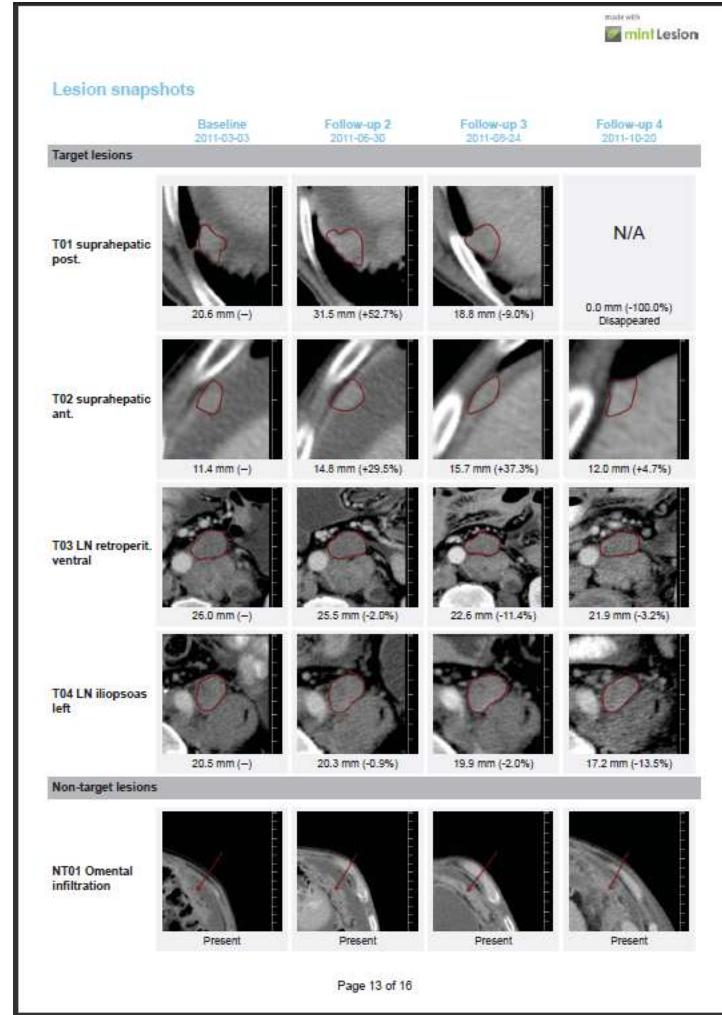
Reference: Strategies for Improving the Value of the Radiology Report: A Retrospective Analysis of Errors in Formally Over-read Studies. S. Kabadi; A. Krishnaraj. J Am Coll Radiol 2017;14:459-466.

Sponsor
CRO
Musterstrasse
Musterstadt

Response evaluation report (RECIST 1.1)

66068				
	Baseline 2011-03-03	Follow-up 2 2011-06-30	Follow-up 3 2011-08-24	Follow-up 4 2011-10-20
Target lesions				
T01 suprahepatic post. Peritoneum	20.6 mm (-)	31.5 mm (+52.7%)	18.8 mm (-9.0%)	0.0 mm (-100.0%) Disappeared
T02 suprahepatic ant. Peritoneum	11.4 mm (-)	14.8 mm (+29.5%)	15.7 mm (+37.3%)	12.0 mm (+4.7%)
T03 LN retroperit. ventral	26.0 mm (-)	25.5 mm (-2.0%)	22.6 mm (-11.4%)	21.9 mm (-3.2%)
Lymph node				
T04 LN iliopsoas left Lymph node	20.5 mm (-)	20.3 mm (-0.9%)	19.9 mm (-2.0%)	17.2 mm (-13.5%)
Non-target lesions				
NT01 Omental infiltration	Present	Present	Present	Present
Omentum				
NT02 peritoneal node suprahepatic Peritoneum	Undefined	New	Present	Disappeared
NT03 peritoneal node lateral right Peritoneum	Undefined	Undefined	New	Present
NT04 Segm VI lateral Liver	Undefined	Undefined	New	Present
NT05 Pleural node left Pleura	Undefined	Undefined	Undefined	New
NT06 bone lumbar 1 Bone	Present	Present	Present	Present
Findings				
F01 Ascites Peritoneum	Defined	Defined	Defined	Defined
F02 Pleural effusion left Pleura	Undefined	Undefined	Undefined	Defined
Evaluation				
Target sum	78.6 mm (-)	92.2 mm (+17.2%)	77.0 mm (-2.1%)	51.1 mm (-33.7%)
Target response	Undefined	Stable Disease	Stable Disease	Partial Response
Non-target response	Undefined	Progressive Disease	Progressive Disease	Progressive Disease
Timepoint response	Undefined	Progressive Disease	Progressive Disease	Progressive Disease
Approval	Approved	Approved	Approved	Approved

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Structured Radiology Report

Example: RECIST 1.1

Table 3**Need for Clinical Information and an Unequivocal Clinical Question**

Survey Question*	Disagree Entirely	Rather Disagree	Disagree (Total)	Neutral	Agree (Total)	Rather Agree	Agree Entirely	Total	Result
C: To make a good report, the radiologist has to know the medical condition of the patient	18 (2.6)	31 (4.4)	49 (7.0)	42 (6.0)	611 (87.0)	332 (47.3)	279 (39.7)	702 (100.0)	Yes (87.0)
R: To make a good report, the radiologist has to know the medical condition of the patient	2 (1.5)	11 (8.2)	13 (9.7)	5 (3.7)	116 (86.6)	41 (30.6)	75 (56.0)	134 (100.0)	Yes (86.6)
C: To make a good report, the radiologist has to know what the clinical question is	3 (0.4)	7 (1.0)	10 (1.4)	8 (1.1)	681 (97.4)	194 (27.8)	487 (69.7)	699 (100.0)	Yes (97.4)
R: To make a good report, the radiologist has to know what the clinical question is	0	1 (0.8)	1 (0.8)	1 (0.8)	131 (98.5)	11 (8.3)	120 (90.2)	133 (100.0)	Yes (98.5)
C: It is better that the radiologist does not know much about the patient, to avoid bias	305 (43.6)	292 (41.7)	597 (85.3)	80 (11.4)	23 (3.3)	19 (2.7)	4 (0.6)	700 (100.0)	No (85.3)
C: Any physician who requests a radiologic examination that is not part of any routine, should state a clear clinical question	1 (0.1)	5 (0.7)	6 (0.9)	26 (3.7)	671 (95.4)	221 (31.4)	450 (64.0)	703 (100.0)	Yes (95.4)

Note.—Data are absolute numbers, and numbers in parentheses are percentages (rounded to the nearest decimal). Statements pertaining to local situations and irrelevant to an international readership have not been included.

* C = referring clinicians (COVER survey), R = radiologists (ROVER survey).

The Radiology Report as Seen by Radiologists and Referring Clinicians: Results of the COVER and ROVER Surveys. Bosmans et. al. ***Radiology***: Volume 259: Number 1—April 2011

Advantage of Clinical Information

- Clinical history does not always = more accurate interpretation
- Study Aim - Prospective blinded study to determine whether clinical information affects the CT report (relatively small sample of 50 patients)
 - The influence of clinical information on the reporting of CT by radiologists. Leslie A, Jones AJ, Goddard PR. Br J Radiol 2000;73: 1052-5.
- Findings –
 - Correct clinical information improved the radiology report
 - Accurate information was beneficial
 - Inaccurate detrimental – lead to bias and incorrect outcomes
 - As complexity of the case increase, the clinical information became more important
- Recall:
 - Clinical Site: Routine Report often referred to when performing research read
 - Central Reads: Well-controlled, very limiting information

Back to Latour

- Bruno Latour – Immutable Mobiles
- Describes how information is passed from between ‘agents’
 - Newspaper, Scientific Publication, **Criteria, Radiology Report**
 - Premise: Easily transported between agents (people/institutions) and has permanence
- Importance:
 - Allows coalition building around an idea
 - Proof (map)
 - More important – **comparable**
 - The act of making an concept permanent through creating a ‘immutable mobile’ does not mean that EXACT information exists or that, for example, the natives are less knowledgeable
 - Unification around an idea

→Radiology Report, Tumor Tracking Form, eCRFs, Data Exports, Images

....Comparable, mutually understood, transportable

Looking at Images: Past, Present, Future – Central Review

Early 2000's	Changes in Technology ~2007 to 2011	Change in how Central Reads Used/Value of Central Reads Questioned (~2011+)
<ul style="list-style-type: none">Images read in batches; sometimes images would be held for years then readCentral read STOPPED at ProgressionImages received from sites ‘in the mail’ – Shipping images and sending labels to the sites and mailing envelopes was a major effort.Central Imaging Reads were used by the sponsor for supporting the endpoint - not provided to the clinical sitesRECIST 1.0, WHO, Cheson Criteria mainly used in oncology	<ul style="list-style-type: none">Started to send images electronicallyNew criteria (irRC) and new treatments (Immuno-Therapy) - stopping reads at Progression no longer made senseRECIST 1.1 published (revision to RECIST 1.0)Immunotherapies became available – Common question “after PD what do we call the assessment if the patient gets better? (i.e. the tumor resolves/improves)” – struggles with how to reportImaging based endpoints – What criteria is used to support the trial? RECIST, irRC, etc?	<ul style="list-style-type: none">Discordance major topicClinical trial sponsors began writing into their protocols that the central readers MUST confirm Progression before site investigator could take the patient off studyCROs requested to do real-time ongoing reads (not batches), real time adjudication, fast turn-arounds, ongoing exports of clean dataRadiology Reads that had errors and/or retrospective data changes had huge consequences to patients/ protocolsCROs directed to send results to sites and support radiology read results to primary investigator

Thank you



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