



PHUSE EU Connect Belfast

DH02

*Tumor assessment evaluation  
using MS Azure and Power BI*

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SBU Oncology  
Oncology Digitalization &  
Computational Science

November 15 2022





# Who? What? How?

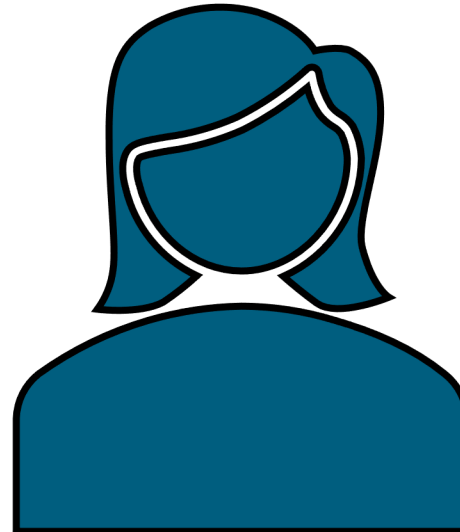
Get to know Mia

This is Mia.

Mia's job is to review tumor data with a focus on completeness and integrity of the tumor data points. If there is unclarity she'll send queries either clarifying uncertainties or correct inconsistencies.

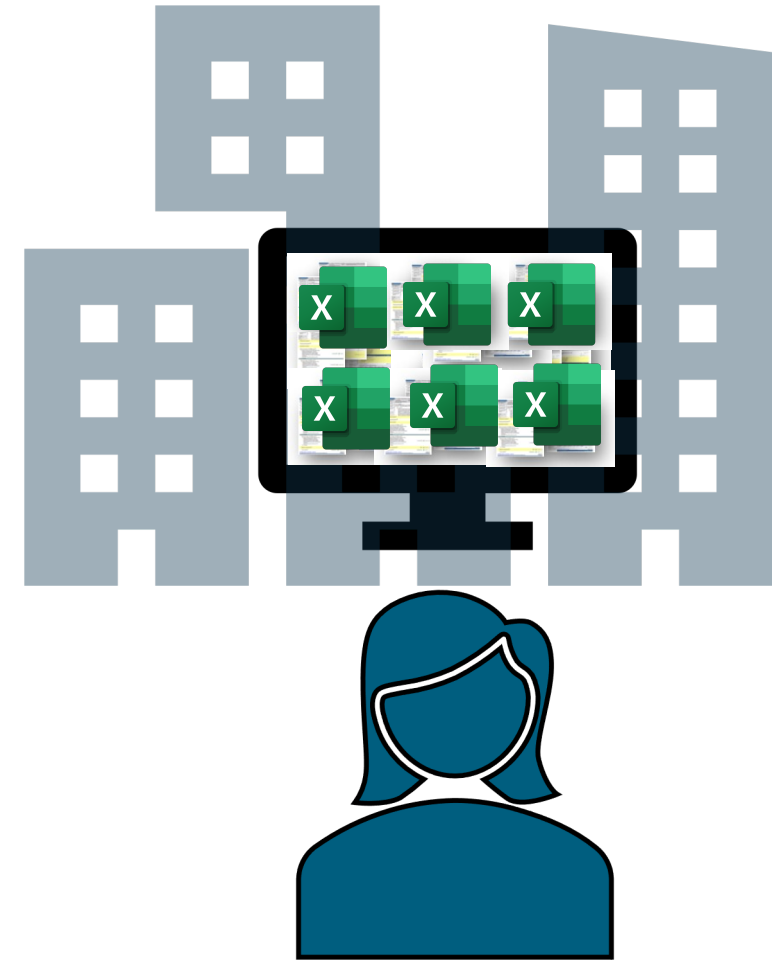
Mia must be very focused while doing her work, she must check every single data point and the combination of them to be able to spot:

- typos
- logical errors
- human error/ entry errors
- missing data



Her objective is to ensure tumor data points are as good as they can be for analysis, especially ahead of protocol-defined analysis milestones.

# Who? What? How?



| Subject                                    |                    | Table         |                        | Response Scale                     |                     | Date           |                            | Assessment          |                             | Sum of Diameters    |                     | Absolute change of Nadir |                            | Percentage Change of Baseline |                  | Percentage Change of Nadir |                           |               |
|--------------------------------------------|--------------------|---------------|------------------------|------------------------------------|---------------------|----------------|----------------------------|---------------------|-----------------------------|---------------------|---------------------|--------------------------|----------------------------|-------------------------------|------------------|----------------------------|---------------------------|---------------|
| 843104161                                  |                    | Calculations  |                        | RECIST 1.1                         |                     | 2018-09-27     |                            | Baseline assessment |                             | 112                 |                     |                          |                            |                               |                  |                            |                           |               |
| 843104161                                  |                    | Calculations  |                        | RECIST 1.1                         |                     | 2018-11-15     |                            | Assessment 1        |                             | 123                 |                     | 11                       |                            | 9,82                          |                  | 9,82                       |                           |               |
|                                            |                    |               |                        | Subject                            | Table               | Lesion Number  | Lesion Location            |                     | Sub-location                | Assessment          | Date                |                          | Method                     |                               | Longest Diameter | Short Axis                 | Reson for Non-Measurement | Other reasons |
|                                            |                    |               |                        | 843104161                          | Target lesions      | 3              | Upper lobe lung            |                     | right upper lobe lesion     | Assessment 1        | 2018-11-15          |                          | CT scan, contrast-enhanced |                               | 39               |                            |                           |               |
|                                            |                    |               |                        | 843104161                          | Target lesions      | 3              | Upper lobe lung            |                     | right upper lobe lesion     | Baseline assessment | 2018-09-27          |                          | CT scan, contrast-enhanced |                               | 30               |                            |                           |               |
|                                            |                    |               |                        | 843104161                          | Target lesions      | 1              | Lung hilum lymph node      |                     | right peri-hilar            | Baseline assessment | 2018-09-27          |                          | CT scan, contrast-enhanced |                               |                  | 29                         |                           |               |
|                                            |                    |               |                        | 843104161                          | Target lesions      | 4              | Celiac lymph node          |                     | celiac adenomegaly          | Baseline assessment | 2018-09-27          |                          | CT scan, contrast-enhanced |                               |                  | 18                         |                           |               |
|                                            |                    |               |                        | 843104161                          | Target lesions      | 1              | Lung hilum lymph node      |                     | right peri-hilar            | Assessment 1        | 2018-11-15          |                          | CT scan, contrast-enhanced |                               |                  | 29                         |                           |               |
|                                            |                    |               |                        | 843104161                          | Target lesions      | 4              | Celiac lymph node          |                     | celiac adenomegaly          | Assessment 1        | 2018-11-15          |                          | CT scan, contrast-enhanced |                               |                  | 18                         |                           |               |
|                                            |                    |               |                        | 843104161                          | Target lesions      | 2              | Lymph node                 |                     | left upper lobe node        | Baseline assessment | 2018-09-27          |                          | CT scan, contrast-enhanced |                               |                  | 35                         |                           |               |
|                                            |                    |               |                        | 843104161                          | Target lesions      | 2              | Lymph node                 |                     | left upper lobe node        | Assessment 1        | 2018-11-15          |                          | CT scan, contrast-enhanced |                               |                  | 37                         |                           |               |
| Subject                                    | Table              | Lesion Number | Lesion Location        | Sub-location                       | Assessment          | Date           | Method                     | Tumor Status        | Treason for Non-Measurement |                     | Other reasons       |                          |                            |                               |                  |                            |                           |               |
| 843104161                                  | Non-target lesions | 1             | Mediastinal lymph node | sub carinar node                   | Assessment 1        | 2018-11-15     | CT scan, contrast-enhanced | Enlargement         |                             |                     |                     |                          |                            |                               |                  |                            |                           |               |
| 843104161                                  | Non-target lesions | 2             | Mediastinal lymph node | numerous mediastinal nodes         | Assessment 1        | 2018-11-15     | CT scan, contrast-enhanced | Enlargement         |                             |                     |                     |                          |                            |                               |                  |                            |                           |               |
| 843104161                                  | Non-target lesions | 3             | Lung hilum lymph node  | right posterior extra-pleural node | Assessment 1        | 2018-11-15     | CT scan, contrast-enhanced | Enlargement         | Subject                     | Trial Unit          | Country             | Treatment                | Cancer type                | Off or On Treatment?          |                  |                            |                           |               |
| 843104161                                  | Non-target lesions | 2             | Mediastinal lymph node | numerous mediastinal nodes         | Baseline assessment | 2018-09-27     | CT scan, contrast-enhanced | Present             | 843104161                   | 04 - 1              | Country 04          | ARM 16                   | Gastric Cancer             | Expected off treatment        |                  |                            |                           |               |
| 843104161                                  | Non-target lesions | 3             | Lung hilum lymph node  | right posterior extra-pleural node | Baseline assessment | 2018-09-27     | CT scan, contrast-enhanced | Present             |                             |                     |                     |                          |                            |                               |                  |                            |                           |               |
| 843104161                                  | Non-target lesions | 4             | Peritoneum             | peritoneal infiltration            | Baseline assessment | 2018-09-27     | CT scan, contrast-enhanced | Present             |                             |                     |                     |                          |                            |                               |                  |                            |                           |               |
| 843104161                                  | Non-target lesions | 1             | Mediastinal lymph node | sub carinar node                   | Baseline assessment | 2018-09-27     | CT scan, contrast-enhanced | Present             |                             |                     |                     |                          |                            |                               |                  |                            |                           |               |
| 843104161                                  | Non-target lesions | 4             | Peritoneum             | peritoneal infiltration            | Assessment 1        | 2018-11-15     | CT scan, contrast-enhanced | Not all evaluated   | Not assessed by radiologist |                     |                     |                          |                            |                               |                  |                            |                           |               |
| 4 <div>/// PHUSE EU Connect 2022 ///</div> |                    |               | Subject                | Table                              |                     | Response Scale |                            | Date                | Assessment                  | Target response     | Non-target Response |                          | Overall response           | Symptomatic Deterioation      |                  |                            |                           |               |
|                                            |                    |               | 843104161              | Response assessment                |                     | RECIST 1.1     |                            | 2018-09-27          | Baseline assessment         |                     |                     |                          |                            | null                          |                  |                            |                           |               |
|                                            |                    |               | 843104161              | Response assessment                |                     | RECIST 1.1     |                            | 2018-11-15          | Assessment 1                | SD                  | PD                  |                          | PD                         | null                          |                  |                            |                           |               |



# *Response Criteria in Oncology / RECIST 1.1*



# RECIST 1.1 in a nutshell

RECIST – Response Evaluation Criteria in Solid Tumors (rev. 1.1)

## Surrogate endpoints...

// ... (instead of OS) reduce time to conclude putative therapeutic benefit of drugs under trial

## Treatment response...

// ... is evaluated using defined response criteria that allow uniform & objective reporting of comparable results & thus evaluation of clinical trials

***„How well does a cancer patient respond to a treatment within a clinical trial?“***

// Does tumor(s) stay the same, shrink / become less or get bigger / become more – by applying objective standardized measurements following a set of agreed rules

## RECIST 1.1...

// ... are the most widely and agreed on rules to assess surrogate endpoints for oncological clinical trials



# RECIST 1.1 ...

...in a nutshell

Baseline assessment

Derive target & non-target response

Derive overall response

RECIST 1.1



## RECIST 1.1 in a nutshell

Baseline assessment

- Tumor needs to be **measurable** (e.g. by CT scans, MRI etc.)
- Measurable lesions at baseline:
  - Non-nodal lesions**  $\geq 10$  mm in **longest diameter**
  - Lymph nodes**  $\geq 15$  mm in **short axis**
- All lesions at baseline must be taken into account
- Define **target lesions** / **non-target lesions**
  - Up to 5 lesions in total / 2 per organ
  - All other lesions non-target



## RECIST 1.1 in a nutshell

Derive target / non-target responses

| Target Response |                                                                                                                                                     |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| CR              | <ul style="list-style-type: none"> <li>All (non-nodal) lesions gone</li> <li>Lymph nodes: short axis <math>&lt; 10</math> mm</li> </ul>             |
| PR              | Sum decreased $\geq 30$ % from baseline                                                                                                             |
| PD              | <ul style="list-style-type: none"> <li>Sum increased <math>\geq 20</math> % from nadir</li> <li>Absolute increase <math>\geq 5</math> mm</li> </ul> |
| SD              | <ul style="list-style-type: none"> <li>Not enough shrinkage for PR</li> <li>Not enough growth for PD</li> </ul>                                     |
| NE              | One or more lesions cannot be evaluated                                                                                                             |

| Non-target Response |                                                                                                                                                    |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| CR                  | <ul style="list-style-type: none"> <li>All (non-nodal) non-target lesions gone</li> <li>Lymph nodes: short axis <math>&lt; 10</math> mm</li> </ul> |
| Non-CR Non-PD       | Any non-target lesions still present, or lymph nodes enlarged                                                                                      |
| PD                  | Unequivocal progression of all non-target lesions, evaluated as a group                                                                            |
| NE                  | One or more lesions cannot be evaluated                                                                                                            |

CR = Complete Response  
PR = Partial Response  
SD = Stable Disease  
PD = Progressive Disease  
NE = Not evaluated / inevaluable



## RECIST 1.1 in a nutshell

Derive overall responses

| Target Lesions | Non-Target Lesions | Overall Response |
|----------------|--------------------|------------------|
| CR             | CR                 | CR               |
| CR             | Non-CR / Non-PD    | No               |
| CR             | NE                 | No               |
| PR             | Anything but PD    | No               |
| SD             | Anything but PD    | No               |
| NE             | Anything but PD    | No               |
| PD             | Any                | Any              |
| Any            | PD                 | Any              |
| Any            | Any                | Yes              |

CR = Complete Response; PR = Partial Response; SD = Stable Disease; PD = Progressive Disease; NE = Not evaluated / inevaluable

E.A. Eisenhauer; P. Therasse; J. Bogaerts; L.H. Schwartz; D. Sargent; R. Ford; J. Dancey; S. Arbuick; S. Gwyther; M. Mooney; L. Rubinstein; L. Shankar; L. Dodd; R. Kaplan; D. Lacombe; J. Verweij (2009), "New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1)", *European Journal of Cancer*, **45** (2): 228–247, [doi:10.1016/j.ejca.2008.10.026](https://doi.org/10.1016/j.ejca.2008.10.026), [PMID 19097774](https://pubmed.ncbi.nlm.nih.gov/19097774/)

E.A. Eisenhauer; P. Therasse; J. Bogaerts; L.H. Schwartz; D. Sargent; R. Ford; J. Dancey; S. Arbuick; S. Gwyther; M. Mooney; L. Rubinstein; L. Shankar; L. Dodd; R. Kaplan; D. Lacombe; J. Verweij (2009), "New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1)", *European Journal of Cancer*, **45** (2): 228–247, [doi:10.1016/j.ejca.2008.10.026](https://doi.org/10.1016/j.ejca.2008.10.026), [PMID 19097774](https://pubmed.ncbi.nlm.nih.gov/19097774/)

# RECIST 1.1 in a nutshell

Need for automation?



- A lot of time of the SMEs (such as Mia) is required to understand, apply and evaluate RECIST rules reliably and spot inconsistencies
- A lot of time is „wasted“ for cleaning and reviewing data, even though their expertise could be better used



- Perfectly suited to **formalize** the **rules into an algorithm** and let a computer spot the differences
- Help SMEs to **save time** and **focus** on the crucial cases (expert confirmation still required!)
- Less time for reviewing consistent cases
- **Speed, reproducibility & reliability gain?** Let's see!





# New Workflow

TDRC / MOCK

OverviewAll Tumor DataTL ReviewNTL ReviewAssessment Revl...Calculation Checks

Subject821101211Cancer TypePancreatic CancerExpected TreatmentExpected off treatmentTreatment GroupARM 21

Case0050All dates consistent?Assessment 1

Target Lesion Information

RECIST calculations and Target lesion response (blue columns contain derived / calculated data)

| Date of procedure | Assessment          | SUMDIAM | Calc Size of TL | Description | % change from Baseline | % change from Baseline Algorithm | Abx Inc from Radio | Abx Inc from Radio Algorithm | % Inc from Radio | % Inc from Radio Algorithm | Response of TL | TL Response Algorithm |
|-------------------|---------------------|---------|-----------------|-------------|------------------------|----------------------------------|--------------------|------------------------------|------------------|----------------------------|----------------|-----------------------|
| 31. Dec. 2018     | Baseline assessment | 58.00   | 58.00           | ✓           |                        |                                  |                    |                              |                  |                            |                |                       |
| 22. Jan. 2019     | Assessment 1        | 123.00  | 123.00          | ✓           | 112.07                 | 112.07                           | 65.00              | 65.00                        | 112.07           | 112.07                     | PD             | PD                    |

RECIST Non-target lesion response (blue columns contain derived / calculated data)

| Date of procedure | Assessment          | new Lesion | Response of non-target/new lesions | NTL Response Algorithm | Description | Overall response RECIST 1.1 | Expected Overall Response | Clinical Progression |
|-------------------|---------------------|------------|------------------------------------|------------------------|-------------|-----------------------------|---------------------------|----------------------|
| 31. Dec. 2018     | Baseline assessment |            |                                    |                        |             |                             |                           | No                   |
| 22. Jan. 2019     | Assessment 1        |            | PD                                 | PD                     | ✓           | PD                          | PD                        | ✓ No                 |

Target Lesions

| Assessment number   | Date of procedure | Anatomical Location                         | Lesion number | Longest diameter | Short Axis | Reason for non-measurement | If others, specify | Potential D <sub>x</sub> | Assessment |
|---------------------|-------------------|---------------------------------------------|---------------|------------------|------------|----------------------------|--------------------|--------------------------|------------|
| Baseline assessment | 31. Dec. 2018     | Lymph node - Lt interlobar LN               | 1.00          | 25.00            |            |                            |                    |                          | All        |
| Assessment 1        | 22. Jan. 2019     | Lymph node - Lt interlobar LN               | 1.00          | 33.00            |            |                            | More than          |                          | Lesion     |
| Baseline assessment | 31. Dec. 2018     | Lymph node - Lt lower neck conglomerated LN | 2.00          | 33.00            |            |                            |                    |                          | All        |
| Assessment 1        | 22. Jan. 2019     | Lymph node - Lt lower neck conglomerated LN | 2.00          | 40.00            |            |                            | More than          |                          | All        |

BackReset PageAlgorithm Guide



# Technical Background

Platform based on  Microsoft Azure Cloud Services &  Azure DevOps Services



ALYCE  
ADVANCED ANALYTICS PLATFORM  
for the CLINICAL ENVIRONMENT

Data

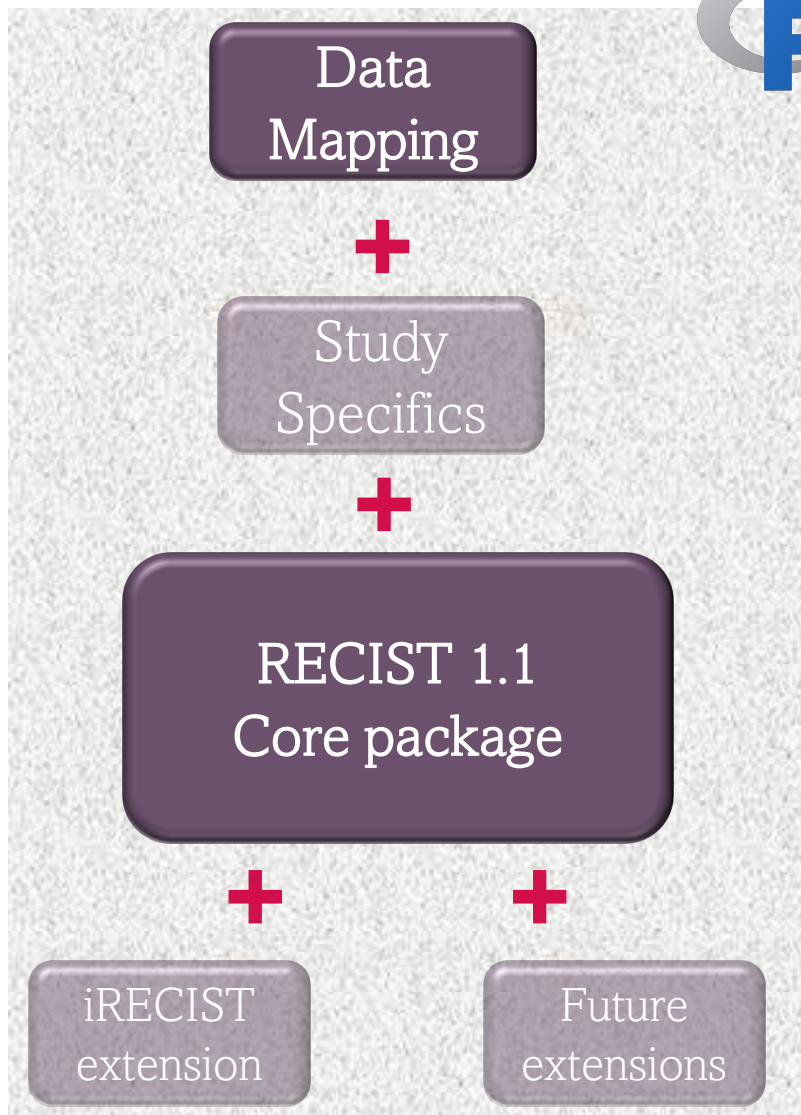
```
Cmd 63
1 # flag to indicate erratic baseline behavior --> erratic baseline can impact all subsequent assessments, will be highlighted in the dashboard using this flag
2
3 flag_BL_inc <- Merged %>%
4   select(SUBJECT_NAME, TUASMTNO, SUMDIAM, calc_sumtl) %>%
5   mutate(
6     calc_sumtl = round(calc_sumtl),
7     inconsistent_BL_flag = if_else(TUASMTNO == 0 & (SUMDIAM != calc_sumtl | !is.na(SUMDIAM) & is.na(calc_sumtl)), 1, 0)) %>%
8   filter(inconsistent_BL_flag == 1) %>%
9   select(SUBJECT_NAME, inconsistent_BL_flag)
10
11 display(flag_BL_inc)
```

▶ (1) Spark Jobs

Table ▾ +

|   | SUBJECT_NAME ▲ | inconsistent_BL_flag ▲ |
|---|----------------|------------------------|
| 1 | 821511331      | 1                      |
| 2 | 823501121      | 1                      |

# Backend Algorithm



## Verbose checks & testing

```

1  ### TL measurement inconsistencies----
2  RECIST_checks_TL <- chk_TL_recist_1_1(
3    tumor_ds = TDRC_recist_target_mrm,
4    filter_tumor_ds = "!is.na(usize)",
5    baseline_assessment_decod = "Baseline assessment"
6  ) # Note: chk_TL_recist_1_1() will produce a list object
7

```

---

```

chk_TL_RECIST_1_1():
Source dataset had 871 rows
Output dataset has 867 rows
New variables created in RECIST_target dataset are [tlloc;pot_datainc_tl]
Below checks are performed.Failed checks are flagged in column- [pot_datainc_tl]
[✓] Check lesion measurement is entered
[✓] Check lesion measurement is entered in right field (Long dia or Short axis)
[✓] Check Baseline measurement is '>= 15' for Nodal lesion and '>=10' for Lesion

```

---

Below are the inconsistencies found, if any

---

```

# A tibble: 5 × 2
  Inconsistencies      n
  <chr>            <int>
1 Lesion too small to be TL      1
2 Longest diameter and short axis were entered for this assessment. Subse...    5
3 Longest diameter was recorded, but lesion is potentially lymph node      2
4 Nodal lesion too small to be TL      2

```

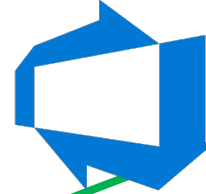
Command took 0.11 seconds -- by clara.beck@bayer.com at 17.10.2022, 17:17:19 on cluster-test-r-package

And user feedback 😊



# Technical Background

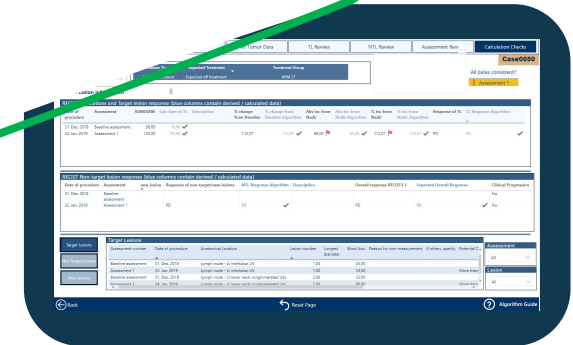
Platform based on Microsoft Azure & Azure DevOps



Coming soon

**GxP qualified platform  
&  
Validated use-case  
implementation**

Using Data Factory



Power BI



# *Power BI User Interface*



## No of Subjects per Treatment Group

| Treatment Group | Subjects   |
|-----------------|------------|
| ARM 00          | 104        |
| ARM 16          | 2          |
| ARM 30          | 2          |
| ARM 32          | 2          |
| ARM 34          | 2          |
| ARM 12          | 1          |
| ARM 13          | 1          |
| ARM 21          | 1          |
| ARM 20          | 1          |
| <b>Total</b>    | <b>127</b> |

## No of Subjects per Cancer Type

| Cancer Type       | Subjects   |
|-------------------|------------|
| Breast Cancer     | 29         |
| Colorectal Cancer | 29         |
| Gastric Cancer    | 24         |
| Lung Cancer       | 20         |
| Bile duct Cancer  | 13         |
| Pancreatic Cancer | 12         |
| <b>Total</b>      | <b>127</b> |

## No of Subjects per Assessment

| Assessment          | Subjects   |
|---------------------|------------|
| Baseline assessment | 127        |
| Assessment 1        | 127        |
| Assessment 2        | 71         |
| Assessment 3        | 30         |
| Assessment 4        | 21         |
| Assessment 5        | 12         |
| Assessment 6        | 9          |
| Assessment 7        | 6          |
| Assessment 8        | 4          |
| <b>Total</b>        | <b>127</b> |

## Subject Listing

| Subjects / BL consistent? |
|---------------------------|
| 812610291 ✓               |
| 812707284 ✓               |
| 821101211 ✓               |
| 821511331 ✗               |
| 821518304 ✓               |
| 822506349 ✓               |
| 823206347 ✓               |
| 823207372 ✓               |
| 823219382 ✓               |
| 823318302 ✓               |
| 823501121 ✗               |
| 823501401 ✓               |
| 823704362 ✓               |
| 823720412 ✓               |
| 823803392 ✓               |
| 831704162 ✗               |

## % of Subjects flagged by TDRC Algorithm by Country and Trial Unit

| Algorithm findings            | Country 01    | Country 02   | Country 03   | Country 04    | Country 05   | Country 06   |
|-------------------------------|---------------|--------------|--------------|---------------|--------------|--------------|
| ⊕ Data inconsistency found    | 3.15%         | 0.79%        | 0.79%        | 3.94%         |              | 1.57%        |
| ⊕ No data inconsistency found | 8.66%         | 7.87%        | 3.15%        | 18.11%        | 1.57%        | 5.51%        |
| <b>Total</b>                  | <b>11.81%</b> | <b>8.66%</b> | <b>3.94%</b> | <b>22.05%</b> | <b>1.57%</b> | <b>7.09%</b> |

## No of Subjects flagged by TDRC Algorithm by Treatment Disposition

| algorithm                     | Expected off treatment | Total      |
|-------------------------------|------------------------|------------|
| ⊕ Data inconsistency found    | 29                     | 29         |
| ⊕ No data inconsistency found | 98                     | 98         |
| <b>Total</b>                  | <b>127</b>             | <b>127</b> |

## No of Subjects per Method of Assessment

| Method of assessment       | Subjects   |
|----------------------------|------------|
| CT scan                    | 66         |
| CT scan, contrast-enhanced | 62         |
| MRI, contrast-enhanced     | 1          |
| Scintigraphy               | 1          |
| <b>Total</b>               | <b>127</b> |

## No of Target Lesion per Subject

| Number of TL | Subjects   |
|--------------|------------|
| 1            | 48         |
| 2            | 48         |
| 3            | 14         |
| 4            | 9          |
| 5            | 7          |
| 6            | 1          |
| <b>Total</b> | <b>127</b> |

## No of Non Target Lesion per Subject

| Number of NTL | Subjects   |
|---------------|------------|
| 0             | 49         |
| 1             | 35         |
| 2             | 22         |
| 3             | 6          |
| 4             | 8          |
| 5             | 2          |
| <b>Total</b>  | <b>127</b> |

## Select Subject for Review

911216004



Back



Reset Page

v20220209



Algorithm Guide

# CASE 0118 / SUBJECT 843104161

This case contains data inconsistency. Subject has 4 Mixed (nodal and non-nodal) TLs. Response expected in TL is stable disease (no increase of at least 20% and at least 5 mm from nadir and no decrease of at least 30% from baseline). Subject has 4 Non-TLs. Scenario for NTL is progressive disease (at least 1 lesion is recorded as 'Enlargement'). Subject has 0 New Lesions. Inconsistency to be flagged is **more than 2 TLs are recorded in the same organ.** This subject has a total of 1 tumor assessments after baseline.

## No of Subjects per Treatment Group

| Treatment Group | Subjects   |
|-----------------|------------|
| ARM 00          | 104        |
| ARM 16          | 2          |
| ARM 30          | 2          |
| ARM 32          | 2          |
| ARM 34          | 2          |
| ARM 12          | 1          |
| ARM 13          | 1          |
| ARM 21          | 1          |
| ARM 20          | 1          |
| <b>Total</b>    | <b>127</b> |

## No of Subjects per Cancer Type

| Cancer Type       | Subjects   |
|-------------------|------------|
| Breast Cancer     | 29         |
| Colorectal Cancer | 29         |
| Gastric Cancer    | 24         |
| Lung Cancer       | 20         |
| Bile duct Cancer  | 13         |
| Pancreatic Cancer | 12         |
| <b>Total</b>      | <b>127</b> |

## No of Subjects per Assessment

| Assessment          | Subjects   |
|---------------------|------------|
| Baseline assessment | 127        |
| Assessment 1        | 127        |
| Assessment 2        | 71         |
| Assessment 3        | 30         |
| Assessment 4        | 21         |
| Assessment 5        | 12         |
| Assessment 6        | 9          |
| Assessment 7        | 6          |
| Assessment 8        | 4          |
| <b>Total</b>        | <b>127</b> |

## Subject Listing

| Subjects / BL consistent? |
|---------------------------|
| 823207372 ✓               |
| 823219382 ✓               |
| 823318302 ✓               |
| 823501121 ✗               |
| 823501401 ✓               |
| 823704362 ✓               |
| 823720412 ✓               |
| 823803392 ✓               |
| 831104102 ✗               |
| 833C04425 ✓               |
| 843104161 ✗               |
| 863502131 ✗               |
| 911016004 ✓               |
| 911216004 ✓               |
| 911501001 ✓               |
| 911502001 ✓               |
| 911503001 ✓               |

## % of Subjects flagged by TDRC Algorithm by Country and Trial Unit

| Algorithm findings          | Country 01    | Country 02   | Country 03   | Country 04    | Country 05   | Country 06   |
|-----------------------------|---------------|--------------|--------------|---------------|--------------|--------------|
| Data inconsistency found    | 3,15%         | 0,79%        | 0,79%        | 3,94%         |              | 1,57%        |
| No data inconsistency found | 8,66%         | 7,87%        | 3,15%        | 18,11%        | 1,57%        | 5,51%        |
| <b>Total</b>                | <b>11,81%</b> | <b>8,66%</b> | <b>3,94%</b> | <b>22,05%</b> | <b>1,57%</b> | <b>7,09%</b> |

## No of Subjects flagged by TDRC Algorithm by Treatment Disposition

| algorithm                   | Expected off treatment | Total      |
|-----------------------------|------------------------|------------|
| Data inconsistency found    | 29                     | 29         |
| No data inconsistency found | 98                     | 98         |
| <b>Total</b>                | <b>127</b>             | <b>127</b> |

## No of Subjects per Method of Assessment

| Method of assessment       | Subjects   |
|----------------------------|------------|
| CT scan                    | 66         |
| CT scan, contrast-enhanced | 62         |
| MRI, contrast-enhanced     | 1          |
| Scintigraphy               | 1          |
| <b>Total</b>               | <b>127</b> |

## No of Target Lesion per Subject

| Number of TL | Subjects   |
|--------------|------------|
| 1            | 48         |
| 2            | 48         |
| 3            | 14         |
| 4            | 9          |
| 5            | 7          |
| 6            | 1          |
| <b>Total</b> | <b>127</b> |

## No of Non Target Lesion per Subject

| Number of NTL | Subjects   |
|---------------|------------|
| 0             | 49         |
| 1             | 35         |
| 2             | 22         |
| 3             | 6          |
| 4             | 8          |
| 5             | 2          |
| <b>Total</b>  | <b>127</b> |

## Select Subject for Review

843104161



## CASE 0118 / SUBJECT 843104161

This case contains data inconsistency. Subject has 4 Mixed (nodal and non-nodal) TLs. Response expected in TL is stable disease (no increase of at least 20% and at least 5 mm from nadir and no decrease of at least 30% from baseline). Subject has 4 Non-TLs. Scenario for NTL is progressive disease (at least 1 lesion is recorded as 'Enlargement'). Subject has 0 New Lesions. Inconsistency to be flagged is **more than 2 TLs are recorded in the same organ.** This subject has a total of 1 tumor assessments after baseline.

Subject

843104161

Cancer Type

Gastric Cancer

Expected Treatment

Expected off treatment

Treatment Group

ARM 16

Subject has more than 2 lesions per organ

Subject has 4 TL(s)

Case0118

TL #1

Lung hilum lymph node - right peri-hilar

| Assessment Number   | Date of procedure | Longest Diameter | Short Axis |
|---------------------|-------------------|------------------|------------|
| Baseline assessment | 27. Sep. 2018     |                  | 29,00      |
| Assessment 1        | 15. Nov. 2018     |                  | 29,00      |

TL #2

Lymph node - left upper lobe node

| Assessment Number   | Date of procedure | Longest Diameter | Short Axis |
|---------------------|-------------------|------------------|------------|
| Baseline assessment | 27. Sep. 2018     |                  | 35,00      |
| Assessment 1        | 15. Nov. 2018     |                  | 37,00      |

TL #3

Upper lobe lung - right upper lobe lesion

| Assessment Number   | Date of procedure | Longest Diameter | Short Axis |
|---------------------|-------------------|------------------|------------|
| Baseline assessment | 27. Sep. 2018     |                  | 30,00      |
| Assessment 1        | 15. Nov. 2018     |                  | 39,00      |

TL #4

Celiac lymph node - celiac adenomegaly

| Assessment Number   | Date of procedure | Longest Diameter | Short Axis |
|---------------------|-------------------|------------------|------------|
| Baseline assessment | 27. Sep. 2018     |                  | 18,00      |
| Assessment 1        | 15. Nov. 2018     |                  | 18,00      |

TL #5

(Blank)

| Assessment Number | Date of procedure | Longest Diameter | Short Axis |
|-------------------|-------------------|------------------|------------|
|                   |                   |                  |            |

Additional TLs

| Lesion Number | Assessment Number | Date of procedure | Anatomical l |
|---------------|-------------------|-------------------|--------------|
|               |                   |                   |              |

## Response Assessment - RECIST 1.1

| Date of procedure | Assessment number   | Sum of Diameters | % change from baseline | Abs increase from nadir | % increase from nadir | Response TL | Response of NTL | Overall Response |
|-------------------|---------------------|------------------|------------------------|-------------------------|-----------------------|-------------|-----------------|------------------|
| 27. Sep. 2018     | Baseline assessment | 112,00           |                        |                         |                       |             |                 |                  |
| 15. Nov. 2018     | Assessment 1        | 123,00           | 9,82                   | 11,00                   | 9,82                  | SD          | PD              | PD               |

## Assessment

All



# *Summary & Outlook*

# Summary & Outlook



**Scalable & Flexible**  
→ Modular package approach

**User centered & sustainable**  
→ Close collaboration, clear need

**Time savings & decreased error probability**  
→ Automation, algorithm

**Appealing UX**  
→ Dashboard approach, process oriented

## More to come...

... extensions to more studies  
... leverage full automation capabilities of MS Azure  
... extension to more tumor classification systems





# Acknowledgements





PHUSE EU Connect Belfast

DH02

*Tumor assessment evaluation  
using MS Azure and Power BI*

*Thank you!*



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I'm happy now!