Bone Metastasis Registry

Manual

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1 Information about the registry

The Bone Metastasis Registry is a unique international collaboration among well renowned cancer centers. The main interest is to collect patient data that will allow scientific studies of good quality and make international comparisons of treatments and outcome possible.

PATHFx is a clinical decision support tool capable of estimating survival in patients with metastatic bone disease. The tool helps physicians individualize treatments, like whether to offer surgery or not, and whether a more durable and expensive implant may be necessary. This decision support enables highly accurate individual patient treatment decisions, support patient-centered care, improve quality of life and lower healthcare costs.

PATHFx is based on machine learning artificial intelligence technology and is integrated in the Bone Metastasis Registry. This allows us to improve prognostic information, over time, to ensure that PATHFx remains clinically relevant, even as medical therapy and treatment philosophies evolve.

Contact information

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2 Login

To log in you need a Yubikey (a strong two factor authentication device). Contact rikard.wedin@sll.se for more information.

1. Go to this web site:
   https://rcc.incanet.se/

   Logga in med Yubikey

   Logga in med SITHS

   Figure 1 Log in phase

2. Click on the 'Logga in med Yubikey' button.
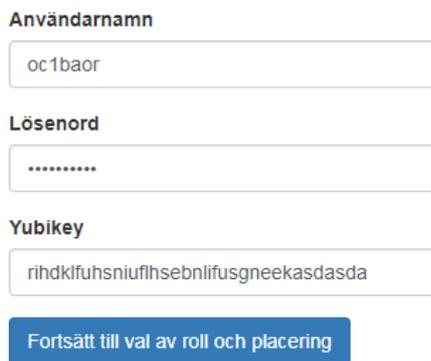
   Användarnamn

   oc1baor

   Lösenord

   ··········

   Yubikey

   rihdklfuhsniuflhsebnlifusgneekasdasda

   Fortsätt till val av roll och placering

   Figure 2 Log in phase

3. Enter your username in the 'Användarnamn' field.

   Enter your password in the 'Lösenord' field.

   Mark the 'Yubikey' field and press the green circle on the Yubikey to generate a one-time password.

   If everything is correct you are now logged in.

   If you are not automatically logged in, click on the blue 'Fortsätt till val av roll och placering' button.

3 Start page

The start page consists of three sections (figure 3) as well as two buttons at the top right corner for registering a new patient and a link to a site where registry documents can be found.
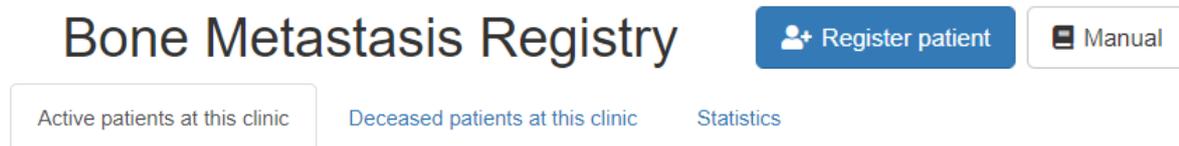

Figure 3 Start page of the registry

1. Active patients at this clinic
   This tab shows a list of active patients registered at your clinic.

2. Deceased patients at this clinic
   This tab shows a list of deceased patients registered at your clinic.

3. Statistics
   This tab shows reports and other statistics.

4. Register patient
   Here you register new patients.
   If you have already started a registration for a patient, the information is accessed from either the 'Active patients at this clinic' tab or the 'Deceased patients at this clinic' tab. Only start a new registration if it is a completely new patient. Once a patient is registered they will appear in one of the two tabs described above.

5. Manual
   This tab contains the user help documents about how to register patients (including this document).

3.1 Active patients at this clinic

This is the default tab that is shown when you log in. All active patients registered at your clinic are listed here under the following headers (as shown in figure 4).

Identifier: When registering a new patient, a unique code is created. This code is shown here.
Gender: The gender of the patient. Can either be Female or Male.
Last updated: The date (YYYY-MM-DD) when the information for this patient was last updated (after clicking 'Save').

Active patient registrations

↺ Reset filters

Identifier	Gender	Last updated
	Any ▾	
BoneMet-DMO-1-0003	Female	2020-05-06
BoneMet-DMO-1-0004	Male	2020-05-06
BoneMet-DMO-1-0005	Male	2019-02-19

Figure 4 Example of the tab 'Active patients at this clinic'

To access the form for the patient, click anywhere in the patient row.

Each header (Identifier, Gender, and Last updated) can be clicked on to sort the list accordingly. Click again to reverse the order.

Each search field can be used to filter the list. Click in a field and type something followed by [Return] to activate the filter. Multiple fields can be used at the same time.

To clear a search field, remove the text and press [Return]. All registered entries for that header will then be shown again.
To clear all filters, click the 'Reset filters' button just over the headers. All registered entries will then show again.

The sorting and filters will be automatically removed when you log out, after which all patients will be visible again.

3.2 Decease patients at this clinic
Here you can see all deceased patients registered at your clinic. They are listed under the following headers (as shown in figure 5).

Identifier: When registering a new patient, a unique code is created. This code is shown here.
Gender: The gender of the patient. Can either be Female or Male.
Last updated: The date (YYYY-MM-DD) when the information for this patient was last updated (after clicking 'Save').
Date of death: Whether the patient is registered as deceased or not (shows as 'Yes' or 'No').

Deceased patient registrations

Identifier	Gender	Last updated	Date of death
	Any ▾		
BoneMet-DMO-1-0001	Male	2020-05-05	2019-03-01
BoneMet-DMO-1-0007	Male	2018-04-26	2020-03-02
BoneMet-DMO-1-0008	Male	2019-02-26	2018-05-08

Figure 5. Example of the tab 'Deceased patients at this clinic'

To access the form for the patient, click anywhere in the patient row.

To filter or sort the list, see chapter 3.2.

3.3 Register patient

To register a new patient, you need to register a unique identifier. To do this just type in your chosen unique number (with a maximum of four characters) and the rest of the sequence will be filled in automatically (see figure 6).

Register new patient ×

BoneMet-DMO-1-NNNN   🔍

Figure 6 Register a new patient

In this example, you would type in *45* as the number and then *BoneMet-DMO-1-0045* will be shown. If the identifier is already allocated, you will see a warning and the option to either continue registering the already existing patient or cancel the registration (see figure 7).

The patient already has an existing registration in SkeletalMetastases

Identifier: BoneMet-DMO-1-0045

Cancel   Open existing registration

Figure 7 Example of an Identifier already registered.

If you enter a unique Identifier you will see a dialogue window where you can register the date of birth (optional) and gender (mandatory) (see figure 8).

Click 'Continue' to start registering data, or 'Cancel' to remove the registration completely.

See section 4 'The form' on how to register data for the patient.

Add new patient (BoneMet-DMO-1-0765) to INCA

No patient with the identifier **BoneMet-DMO-1-0765** was found on INCA. You may create a new patient manually in this step.

Date of birth

| YYYY-MM-DD | 📅 |

Gender

| - Select - ▾ |

Cancel   Continue

Figure 8 Register patient information

3.4 Manual

Here you will find this manual.

3.5 Statistics

Here you will find several reports.

4 The form

At the top of the form there is a summary of basic information about the patient. To show/hide the information, click on the grey frame with the Identifier.

Underneath are six tabs where the registration takes place. See each respective chapter below for more information about the variables.

Figure 9 Example of patient information

4.1 Primary data

Variable	Information
Primary tumor	One of the following must be chosen: **Breast** **Lung** **Prostate gland** **Kidney** **Myeloma** **Lymphoma** **Liver** **Gastric** **Thyroid gland** **Melanoma** **Colorectal** **Bladder** **Female genital organs** **Sarcoma** **Squamous cell carcinoma** **Unknown** **Other** (free text box will be shown)

Specify type
(The list for specifying type depends on which 'Primary tumor' has been selected)
	For some of the above primary tumors, you must select a tumor type. One of the following for the respective primary tumor must be chosen:
	
	Lung: **Non-small cell**
	          Small cell
	          Unknown

Variable	Information
Lymphoma:	**Lymph node of head, face and neck**
	Intrathoriacic lymph nodes
	Intra-abdominal lymph nodes
	Lymph nodes of axilla or arm
	Lymph nodes of inguinal region or leg
	Pelvic lymph nodes
	Lymph nodes of multiple regions
	Lymph node, NOS
	Unknown
Gastric:	**Esophagus**
	Stomach
	Unknown
Melanoma:	**Skin melanoma**
	Connective, subcutaneous and other soft tissues
	Unknown
Colorectal:	**Colon**
	Rectosigmoid junction
	Rectum
	Unknown
Female genital organs:	**Cervix uteri**
	Corpus uteri
	Ovary
	Unknown
Anaplastic Lymphoma Kinase (ALK) (Only visible if non-small cell lung cancer is chosen as primary tumor)	One of the following may be chosen: **Yes** **No**
Epidermal Growth Factor Receptor (EGFR) (Only visible if non-small cell lung cancer is chosen as primary tumor)	One of the following may be chosen: **Yes** **No**
Date of birth	Date of birth of the patient (YYYY-MM-DD)
Date of diagnosis	Date of diagnosis of the primary tumor (YYYY-MM-DD)
Biological therapy	One of the following may be chosen: **Checkpoint inhibition** **Targeted therapy for a genetic mutation** **Adaptive immunotherapy** **Other** (free text box will be shown)
Drug / Medicine	Specify drug / medicine
Biological response	One of the following may be chosen: **Responder** **Non-responder** **Equivocal**
Patient deceased	Date of death of the patient (YYYY-MM-DD)
Cause of death (Only visible if 'Patient deceased' variable has a date registered)	One of the following must be chosen: **Due to cancer** **Other reason**

4.2 Metastases locations

Press 'Add Location' to start registering the metastases location (multiple entries can be added). For each metastasis location, surgery and radiotherapy are registered later (see section 4.3 and 4.4)

Variable	Information
Bone	The bone receiving metastasis treatment. One of the following must be chosen: **Femur** **Humerus** **Tibia** **Pelvis** **Scapula** **Spine** **Other** (free text box will be shown)
Bone location (This list will vary according to the 'Bone' selected in the previous section)	One of the following bone locations must be chosen for each previously selected 'Bone'.
Femur:	**Head** **Neck** **Intertrochanteric** **Subtrochanteric** **Diaphysis** **Distal**
Humerus:	**Head** **Neck** **Diaphysis** **Distal**
Tibia:	**Epiphysis** **Metaphysis** **Diaphysis** **Distal**
Pelvis:	**Acetabulum** **Os ileum** **Os pubis**
Scapula:	**Body/Spine** **Coracoid** **Acromion** **Glenoid**
Spine:	**Cervical** **Thoracic** **Lumbar**
Other:	**Proximal** **Diaphysis** **Distal** **Not applicable**
Side	For every location, a side must be chosen. **Right** **Left** **Not applicable**
Image	Upload an optional DICOM image for each metastasis location. The image can be removed by clicking 'Remove image'. When the form is saved a link will be created here where the image can be downloaded from.
Image comment	Add an optional comment to the uploaded DICOM image.

4.3 Surgery

If surgery has been performed, this is where you register that information for each of the relevant metastases locations already registered in section 4.2.

Press 'Add Surgery' or 'Add reoperation' to start registering (multiple entries can be added). A reoperation must be linked to a main surgery and a date for the reoperation must be registered (see figure 10). If there is no main surgery registered, a reoperation cannot be registered.

Figure 10 Register a reoperation.

Variable	Information
Surgeon	Name of the surgeon who performed the surgery.
Surgery date	Date of surgery (YYYY-MM-DD).
Metastasis location	Choose the relevant metastasis location where surgery has been performed (if this list is empty no location has yet been registered. See section 4.2)
Age at surgery	Age at time of surgery should be entered if not automatically generated.
Metastases at the time of surgery	Click 'Add Metastases' to add types of metastases. Multiple entries can be added. **Skeletal is always selected.** The following can also be chosen: **Brain** **Liver** **Lung** **Lymph node** **Skeletal** **Other** (free text box will be shown) **Unknown**
Number of skeletal metastases	Number of skeletal metastases. One of the following must be chosen: **Multiple** **Solitary** **Unknown**
Surgeons estimation of survival pre-surgery (number of months)	Estimation of survival (in months)
Lab Data (click 'Add Lab Data' to register)	
Date	Date of laboratory testing (YYYY-MM-DD).

Variable	Information
ALB	Preoperative Albumin (ALB) in g/L, within one week before the procedure; typical range (~34-45). For USA centers in which g/dL is used, multiply by 10 to convert to g/L. For instance an ALB value of 4 g/dL = 40 g/L
ALP	Preoperative Alkaline Phosphatase (ALP) in U/L, within one week before the procedure. Typical range (~50-500)
CRP	Preoperative C-Reactive Protein (CRP) in mg/L, within one week before the procedure. Typical range (~0–100)
ESR	Preoperative Erythrocyte Sedimentation Rate (ESR) in mm/hour, within one week before the procedure. Typical range (~0-50)
HB	Preoperative Hemoglobin (HB) in g/L, within one week before the procedure. Typical range (~50-180). For USA centers in which g/dL is used, multiply by 10 to convert to g/L. For instance, a HB Value of 10 g/dL = 100 g/L
ALC	Preoperative Absolute Lymphocyte Count in 10^9 cells / L, within one week before the procedure. Typical range (~0-4). 10^9 cells / L is equivalent to other units commonly used in the USA such as K/mm3 or K/µL.
Promis (click 'Add Promis' to register)	
Date for Promis	Date of Promis survey (YYYY-MM-DD).
Type	Type of Promis. One of the following must be chosen: **Preop** **One month postop (+- 7 days)** **Six months postop (+- 14 days)** **12 months postop (+- 30 days)**
Mobility	Mobility score
Physical Function	Physical function score
Upper Extremity	Upper extremity score
Pain Behavior	Pain behavior score
Pain Inference	Pain inference score
Performance Status (click 'Add Performance Status' to register)	
Date of status	Date of performance status (YYYY-MM-DD).
ASA status	Status per ASA. One of the following must be chosen: **1. A normal healthy patient** **2. A patient with mild systemic disease** **3. A patient with severe systemic disease** **4. A patient with severe systemic disease that is a constant threat to life** **5. A moribund patient who is not expected to survive without the operation**
ECOG status	Status per ECOG. One of the following must be chosen: **0 Fully active, able to carry on all pre-disease performance without restriction** **1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature** **2 Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours** **3 Capable of only limited selfcare, confined to bed or chair more than 50 % of waking hours**

Variable	Information
	4 Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair. **5 Dead**
Karnofsky Status	Status per Karnofsky. One of the following must be chosen: **100 Normal, no complaints** **90 Able to carry on normal activities. Minor signs or symptoms of disease** **80 Normal activity with effort** **70 Care for self. Unable to carry on normal activity or to do active work** **60 Requires occasional assistance, but able to care for most of their needs** **50 Requires considerable assistance and frequent medical care** **40 Disabled. Requires special care and assistance** **30 Severely disabled. Hospitalisation indicated though death non-imminent** **20 Very sick. Hospitalisation necessary. Active supportive treatment necessary** **10 Moribund** **0 Dead**
	Surgery
Main indication	Main indication for surgery. One of the following must be chosen: **Complete fracture, non-spinal** **Impending fracture, non-spinal** **Complete fracture, neurological compromise** **Impending fracture, neurological compromise** **Complete fracture, other reason** (free text box will be shown) **Impending fracture, other reason** (free text box will be shown)
Operation Method	One of the following must be chosen: **Hemi prosthesis** **Prosthesis, total joint replacement** **Prosthesis & acetabular reconstruct** **Mega/tumor prosthesis** **Glide screw plate** **Plate** **Recon nail (cervical screw)** **Intramedullary nail** **Laminectomy & posterior stabilization** **Laminectomy & anterior stabilization** **Laminectomy without stabilization** **Other** (free text box will be shown)
Reason (Only visible if you are registering a reoperation)	One of the following must be chosen: **Non-union** **Local tumor progression** **Stress fracture of bone** **Poor initial fixation (within 6 wks)** **Implant failure** **Technical error** **Prosthetic dislocation** **Wound infection**

Variable	Information
	Deep infection
	Other (free text box will be shown)
Operation strategy	One of the following must be chosen:
	Curettage
	Curettage + cement
	Stabilization without tumor removal
	Marginal excision
	Excision with wide margins
	Other (free text box will be shown)
Local adjuvant treatment	One of the following must be chosen:
	Yes
	No
Type of adjuvant treatment (Only visible if 'Yes' is chosen for Local adjuvant treatment)	One of the following must be chosen:
	Thermalablation
	Cryoablation
	Electrochemotherapy
	Arterial Embolization
	Phenol
	Bisphosphonates
	Combination
	Other (free text box will be shown)
Complication (click 'Add Complication' to register)	
Complication date	Date of complication (YYYY-MM-DD).
Type	One of the following must be chosen:
	Wound infection only
	Deep infection
	Stroke
	Nerve injury
	Myocardial infarction
	Pulmonary embolism
	Pneumonia
	Respiratory failure
	DVT
	Other (free text box will be shown)
PATHFx calculation	
Press 'Calculate PATHFx' to register data based on PATHFx variables (marked in purple) *	
Probability of survival 1 month	Will automatically be set from the performed calculation.
Probability of survival 3 month	Will automatically be set from the performed calculation.
Probability of survival 6 month	Will automatically be set from the performed calculation.
Probability of survival 12 month	Will automatically be set from the performed calculation.
Probability of survival 18 month	Will automatically be set from the performed calculation.
Probability of survival 24 month	Will automatically be set from the performed calculation.
Calculation date	Date when the calculation was performed.
Comment	Add an optional comment on the calculation.

* After pressing 'Calculate PATHFx' a summary of the registered variables is shown. Here you will have a last opportunity to change anything (press 'Cancel') or proceed with the calculation (press 'OK').

Proceed with the calculation?

×

Is it ok to proceed with the calculation based on the following values?

Variable	Value
Gender	female
ECOG status	<=2
Primary tumor	unknown
Bone metastases	solitary
Visceral metastases	yes
Complete bone fracture	no
Lymph node metastases	no
Hemoglobin	7.6
ALC	3.4
Surgeon estimate of survival	6

Cancel   Ok

Figure 11 Example of the summary of registered data for the PATHFx variables, from the 'Surgery' tab

4.4 Radiotherapy

If radiotherapy has been performed, this is where you register that information for each relevant metastasis location already registered in section 4.2.

Press 'Add Radiotherapy' to start registering (multiple entries can be added).

Variable	Information
Physician	Name of the physician responsible for the radiotherapy.
Radiotherapy date	Date of radiotherapy treatment (YYYY-MM-DD).
Metastasis location	Choose the relevant metastasis location where radiotherapy has been performed (if this list is empty no location has yet been registered. See section 4.2)
Age at radiotherapy	Age at time of radiotherapy should be entered if not automatically generated.
Metastases at the time of radiotherapy	Click 'Add Metastases' to add types of metastases. **Skeletal must always be selected.** The following can also be chosen: **Brain** **Liver** **Lung** **Lymph node** **Skeletal** **Other** (free text box will be shown) **Unknown**

Variable	Information
Number of skeletal metastases	Number of skeletal metastases. One of the following must be chosen: **Multiple** **Solitary** **Unknown**
Physicians estimation of survival pre-radiotherapy (number of months)	Estimation of survival (in months)
Lab Data (click 'Add Lab Data' to register)	
Date	Date of laboratory testing (YYYY-MM-DD).
ALB	Preoperative Albumin (ALB) in g/L, within one week before the procedure; typical range (~34-45). For USA centers in which g/dL is used, multiply by 10 to convert to g/L. For instance, an ALB value of 4 g/dL = 40 g/L
ALP	Preoperative Alkaline Phosphatase (ALP) in U/L, within one week before the procedure. Typical range (~50-500)
CRP	Preoperative C-Reactive Protein (CRP) in mg/L, within one week before the procedure. Typical range (~0–100)
ESR	Preoperative Erythrocyte Sedimentation Rate (ESR) in mm/hour, within one week before the procedure. Typical range (~0-50)
HB	Preoperative Hemoglobin (HB) in g/L, within one week before the procedure. Typical range (~50-180). For USA centers in which g/dL is used, multiply by 10 to convert to g/L. For instance, a HB Value of 10 g/dL = 100 g/L
ALC	Preoperative Absolute Lymphocyte Count in 10^9 cells / L, within one week before the procedure. Typical range (~0-4). 10^9 cells / L is equivalent to other units commonly used in the USA such as K/mm3 or K/µL.
Promis (click 'Add Promis' to register)	
Date for Promis	Date of Promis survey (YYYY-MM-DD).
Type	Type of Promis. One of the following must be chosen: **Preop** **One month postop (+- 7 days)** **Six months postop (+- 14 days)** **12 months postop (+- 30 days)**
Mobility	Mobility score
Physical Function	Physical function score
Upper Extremity	Upper extremity score
Pain Behavior	Pain behavior score
Pain Inference	Pain inference score
Performance Status (click 'Add Performance Status' to register)	
Date of status	Date of performance status (YYYY-MM-DD).
ECOG status	Status per ECOG. One of the following must be chosen: **0 Fully active, able to carry on all pre-disease performance without restriction** **1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature** **2 Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours** **3 Capable of only limited selfcare, confined to bed or chair more than 50 % of waking hours**

Variable	Information
	4 Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair. **5 Dead**
Karnofsky Status	Status per Karnofsky. One of the following must be chosen: **100 Normal, no complaints** **90 Able to carry on normal activities. Minor signs or symptoms of disease** **80 Normal activity with effort** **70 Care for self. Unable to carry on normal activity or to do active work** **60 Requires occasional assistance, but able to care for most of their needs** **50 Requires considerable assistance and frequent medical care** **40 Disabled. Requires special care and assistance** **30 Severely disabled. Hospitalisation indicated thought death non-imminent** **20 Very sick. Hospitalisation necessary. Active supportive treatment necessary** **10 Moribund** **0 Dead**
	Radiotherapy
Pre-op radiotherapy	One of the following must be chosen: **No** **Yes** **Unknown**
Pre-op radiotherapy date - Start date	(YYYY-MM-DD).
Pre-op radiotherapy date - Stop date	(YYYY-MM-DD).
Total dose (gray)	
Number of fractions	
Post op radiotherapy	One of the following must be chosen: **No** **Yes** (If Yes, please chose which (previously registered) surgery the post-op radiotherapy belongs to.) **Unknown**
Post-op radiotherapy date - Start date	(YYYY-MM-DD).
Post-op radiotherapy date - Stop date	(YYYY-MM-DD).
Total dose (gray)	
Number of fractions	
Radiotherapy alone	One of the following must be chosen: **No** **Yes** **Unknown**
Main indication	Main indication for radiotherapy. One of the following must be chosen: **Complete fracture, non-spinal** **Impending fracture, non-spinal** **Complete fracture, neurological compromise** **Impending fracture, neurological compromise** **Complete fracture, other reason** (free text box will be shown) **Impending fracture, other reason** (free text box will be shown)

Variable	Information
Radiotherapy date - Start date	(YYYY-MM-DD).
Radiotherapy date - Stop date	(YYYY-MM-DD).
Total dose (gray)	
Number of fractions	
PATHFx (only visible for 'Radiotherapy Alone')	
Press 'Calculate PATHFx' to register data based on PATHFx variables (marked in red) *	
Probability of survival 1 month	Will automatically be set from the performed calculation.
Probability of survival 3 month	Will automatically be set from the performed calculation.
Probability of survival 6 month	Will automatically be set from the performed calculation.
Probability of survival 12 month	Will automatically be set from the performed calculation.
Probability of survival 18 month	Will automatically be set from the performed calculation.
Probability of survival 24 month	Will automatically be set from the performed calculation.
Comment	Add an optional comment on the calculation.

* After pressing 'Calculate PATHFx' a summary of the registered variables is shown. Here you will have a last opportunity to change anything (press 'Cancel') or proceed with the calculation (press 'OK').

4.5 PATHFx

Here you will see a summary for all the completed PATHFx calculations.

PATHFx Calculations

	1 month	3 months	6 months	12 months	18 months	24 months	Calculation date	Comment
Surgery - 2019-05-05	92%	49%	28%	22%	18%	13%	2020-04-30	

Figure 12 Example of PATHFx summary

4.6 Comments

Press 'Add Comment' to register comments (multiple entries can be added).

Variable	Information
Comment date	Date of comment (YYYY-MM-DD).
Commented by	Person making the comment
Comment	Comment