

Manual for the Pituitary Disease-Specific Module

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Outcome = a dataset at a certain timepoint during the follow-up of the patient, could also be referred to as 'return'.

1. Time-points to create an outcome (return)

1.2 General follow-up ('wait-and-scan' policy)

- Create an outcome at the time of diagnosis (before the start of any treatment)
- Create a new outcome 2, 4, 5, 10, 15, 20 etc. years after diagnosis, unless there is progression* or a treatment (other than endocrine replacement) is initiated (see below).

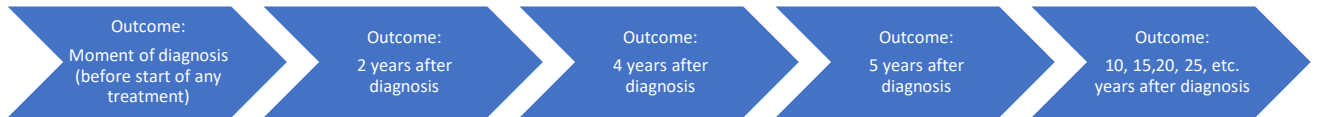


Figure 1 - General follow-up in case of no progression

*In case of progression that is not followed by treatment, create an extra outcome at the time of progression (Figure 2a and 2b).



Figure 2a – Example of general follow-up in case of progression not followed by treatment (3 years after diagnosis)



Figure 2b - Example of general follow-up in case of progression not followed by treatment (6/7/8/9 years after diagnosis)

1.3 Tumour treatment during follow-up

! Beware: **medical tumour treatment** is directed towards **growth/volume reduction** (e.g. such as with dopamine agonists, somatostatin analogues, or temozolamide). Endocrine replacement therapies is **NOT** tumour treatment.

1.3.1 Medical/surgical/radiotherapy tumour treatment

- Create an outcome at the time of diagnosis (before the start of any treatment), see also paragraph 1.2 General follow-up.
- Create a new outcome before the start of treatment if the outcome at the time of diagnosis was more than 6 months ago.
- Create a new outcome 6 months (3-9) after (initiating) medical/surgical/radiotherapy treatment.
- Subsequently, fall back into the outcomes of the general follow-up (see paragraph 1.2), unless there is progression or a new treatment
- If a new treatment is initiated, create a new outcome right before the treatment and 6 months after treatment.

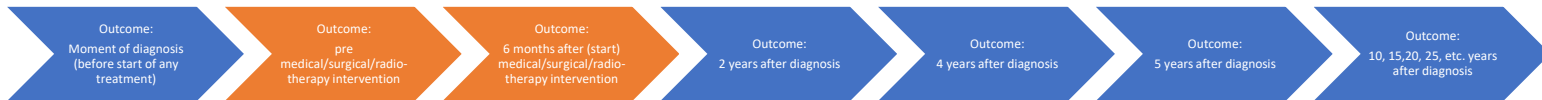


Figure 3 – Example of medical/surgical/radiotherapy treatment started within 2 years after diagnosis

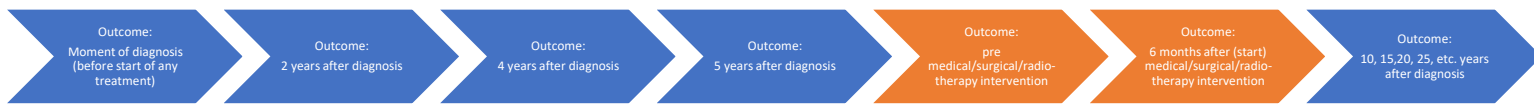


Figure 4 - Example of medical/surgical/radiotherapy treatment started 6/7/8/9 years after diagnosis

1.3.2 Multiple treatment modalities

In case a patient is treated with multiple modalities during their follow-up period, please make sure that you have created an outcome for the moment of diagnoses, 2, 5, 10, 15 years etc. after diagnosis and add treatment specific outcomes (See Figure 5).

At the moment two modalities of treatment are given at the exact same time, these outcomes can be combined.



Figure 5 - Example of surgical therapy within 2 years after diagnosis followed by radiotherapy 3/4 years after diagnosis

2.0 Overview of tabs to be filled in per outcome

Table 1 - Overview of tabs to be filled in per outcome

	Basic disease module	Auxology parameters	Endocrine manifestations	Secreted hormones	Visual impairment	Imaging	Genetics	Histopathology	Radiation	Medical therapy	Surgical outcomes	VTE
Return												
General follow-up: time of diagnosis	X	X	X	X	X	X	X					**
General follow-up: x years after diagnosis	X	X	X	X	X	X	X	*	*	*	*	**
General follow-up: progression not followed by treatment	X	X	X	X	X	X	X					**
Medical tumour treatment: pre-medical intervention	X	X	X	X	X	X	X	*	*	*	*	**
Medical tumour treatment: 6 months after initiating medical intervention	X	X	X	X	X	X	X	*	*	X	*	**
Surgical tumour treatment: pre-surgical intervention	X	X	X	X	X	X	X	*	*	*	*	**
Surgical tumour treatment: 6 months post surgical intervention	X	X	X	X	X	X	X	X	*	*	X	**
Radiotherapy treatment: pre radiotherapy intervention	X	X	X	X	X	X	X	*	*	*	*	**
Radiotherapy treatment: 6 months post radiotherapy	X	X	X	X	X	X	X	*	X	*	*	**

* = only if applicable based on prior treatments, update assessment dates and outcomes

** = only if VTE occurred. Cushing Severity Index at every time point for patients with M. Cushing

3.0 Instructions for Pituitary Tumour Module Tabs

3.1 Tab: Manifestations and secreted hormones

- To be filled in for every outcome to monitor hormone excess and pituitary function loss over time for all patients independent of their treatments.
- In case of remission of hormone secreting adenoma (e.g. Cushing) ‘Cushing disease’ in the ‘Endocrine manifestations’ tab needs to be deselected and ‘Main secreted hormone’ needs to be changed to ‘None’. In case of a recurrence ‘Cushing disease’ and ‘ACTH’ needs to be reselected.
- In case of additional pituitary axis loss as a result of surgery, the additional pituitary axis loss must be selected.

3.2 Tab: Imaging – Tumour behaviour assessed by post-treatment imaging

- The items ‘progression’, ‘increase of maximal tumour diameter’ and ‘increase of tumour volume’ needs to be compared to the last MRI before treatment when filling in a 6 months post-intervention outcome and compared to the first post-intervention MRI if applicable or the MRI at diagnosis when filling in the general follow-up outcomes.

Tumour behaviour assessed by post-treatment imaging

Assessment Date	<input type="text" value="dd-mm-yyyy"/>
Age at Assessment Date	<input type="text"/>
Is there a tumour progression?	- Select -
Has the maximal tumour diameter assessed by post-treatment imaging increased?	- Select -
Has the tumour volume assessed by post-treatment imaging increased?	- Select -
Tumour remnant visible on MRI?	- Select -
Which of the following standard therapies has been used in this patient?	<input type="checkbox"/> Medical therapy <input type="checkbox"/> Surgical therapy <input type="checkbox"/> Radiation therapy

Figure 6 – Fields abouts progression at the section of tumour behaviour assess by post-treatment imaging

3.3 Tab: Radiation

- ‘Endocrine response’ and ‘tumour response’ following radiation therapy have to be **compared to hormone levels (in case of functional adenomas) and imaging right before the initiation of radiation treatment**

3.4 Tab: Genetics

Fill in whenever possible, but **specifically in patients <30 years of age.**

3.5 Tab: Medical therapy

- ‘Endocrine response’ and ‘tumour response’ following radiation therapy have to be **compared to hormone levels (in case of functional adenomas) and imaging right before start of medical treatment**

3.6 Tab: Surgical outcomes

- Endocrine response following surgery has to be **compared to hormone levels (in case of functional adenomas) right before surgery**

Venous thromboembolism (VTE) module

- Fill in every 2-3 years for all pituitary adenomas IF VTE occurred