* 1. Have multiple brain CTs been performed?  Yes  No, single head CT
     1. If YES, how many have been performed?  2  3  4  5  6  >6
     2. If >6 specify:

Table for recording CT results

| Head CT | Date Performed | Age of affected | Where Performed |
| --- | --- | --- | --- |
| 1st | Data to be filled in by site | [derived field] | Data to be filled in by site |
| 2nd | Data to be filled in by site | [derived field] | Data to be filled in by site |
| 3rd | Data to be filled in by site | [derived field] | Data to be filled in by site |

**Technical Information**

1. Name of the scanner manufacturer:

GE Siemens Philips Toshiba Other, specify:

1. Imaging scanner model name:
2. Imaging scanner software name:
3. Imaging scanner software version number:
4. Image acquisition mode:

Helical Sequential

1. Pitch:
2. Image acquisition parameters: kVp:

mA:

1. Slice thickness: mm
2. Slice orientation:
3. Contrast used:  Yes  No
   1. If YES, name of the contrasts: dosage:
4. Clinical read of CTs
   1. Reader blinded to clinical data? Yes  No
   2. Quality of images technically satisfactory? Yes  No  Partially, specify:

**Findings**

1. Lesions found? Yes  No
   1. If YES, type of lesion(s):  Hypodensity  Calcification  Infarct  Hemorrhage
2. If present, location of hypodensity:  Cortical  WM  Caudate  Putamen  Globus pallidus

Thalamic  Brainstem  Cerebellum  Other, specify:

1. White matter involvement
   1. White matter hypodensity:  Absent  Present
      1. If present, indicate location(s) (if diffuse mark all):

Frontal

Parietal

Temporal

Occipital

Subcortical

Periventricular

Deep

Cerebellar

1. Cavitation:  Yes  No
   * 1. If present, indicate location(s):

Frontal

Parietal

Temporal

Occipital

Periventricular

Deep WM

Cerebellar WM

Diffuse

Caudate

Putamen

Globus Pallidus

Thalamic

Brainstem

Other, specify:

1. Acute infarct(s) present:

Definitely present

Equivocal

Definitely absent

1. Number of acute infarcts:
2. Location of acute infarct (Choose all that apply. N/A – Not present should be default response for each region):

Acute Infarcts Location Table

| Brain Region | Side |
| --- | --- |
| Frontal lobe | Right  Left  Bilateral  N/A – Not present |
| Parietal lobe | Right  Left  Bilateral  N/A – Not present |
| Temporal lobe | Right  Left  Bilateral  N/A – Not present |
| Occipital lobe | Right  Left  Bilateral  N/A – Not present |
| Insula | Right  Left  Bilateral  N/A – Not present |
| Cerebellum | Right  Left  Bilateral  N/A – Not present |
| Pons | Right  Left  Bilateral  N/A – Not present |
| Midbrain | Right  Left  Bilateral  N/A – Not present |
| Medulla | Right  Left  Bilateral  N/A – Not present |
| Corona radiata | Right  Left  Bilateral  N/A – Not present |
| Anterior limb IC | Right  Left  Bilateral  N/A – Not present |
| Posterior limb IC | Right  Left  Bilateral  N/A – Not present |
| Caudate | Right  Left  Bilateral  N/A – Not present |
| Globus Pallidus | Right  Left  Bilateral  N/A – Not present |
| Putamen | Right  Left  Bilateral  N/A – Not present |
| Thalamus | Right  Left  Bilateral  N/A – Not present |

1. Chronic infarct(s):
   1. Present?  Yes  No
2. Number of chronic infarcts:
3. Location of chronic infarct (Choose all that apply. N/A – Not present should be default response for each region):

Chronic Infarcts Location Table

| Brain Region | Side |
| --- | --- |
| Frontal lobe | Right  Left  Bilateral  N/A – Not present |
| Parietal lobe | Right  Left  Bilateral  N/A – Not present |
| Temporal lobe | Right  Left  Bilateral  N/A – Not present |
| Occipital lobe | Right  Left  Bilateral  N/A – Not present |
| Insula | Right  Left  Bilateral  N/A – Not present |
| Cerebellum | Right  Left  Bilateral  N/A – Not present |
| Pons | Right  Left  Bilateral  N/A – Not present |
| Midbrain | Right  Left  Bilateral  N/A – Not present |
| Medulla | Right  Left  Bilateral  N/A – Not present |
| Corona radiata | Right  Left  Bilateral  N/A – Not present |
| Anterior limb IC | Right  Left  Bilateral  N/A – Not present |
| Posterior limb IC | Right  Left  Bilateral  N/A – Not present |
| Caudate | Right  Left  Bilateral  N/A – Not present |
| Globus Pallidus | Right  Left  Bilateral  N/A – Not present |
| Putamen | Right  Left  Bilateral  N/A – Not present |
| Thalamus | Right  Left  Bilateral  N/A – Not present |

1. If present, location of hemorrhage:  Lobar, specify:  Caudate  Putamen  Globus Pallidum

Thalamus  Brainstem  Cerebellum  Other, specify:

1. Malformations
   1. Cortical malformations:  Yes  No
      1. If YES, indicate location and specify:

Frontoparietal, specify: Temporal, specify: Occipital, specify:

* 1. Corpus callosum:  Normal  Abnormal
     1. If Abnormal, specify:
  2. Subependymal cysts:  Yes  No
     1. If YES, indicate location(s):

Frontoparietal  Temporal  Occipital

* 1. Ventricles**:**  Normal  Abnormal
     1. If Abnormal**,** specify:

Dilation  Other, specify:

* 1. Brainstem:  Normal  Abnormal
     1. If Abnormal, specify:
  2. Cerebellum:  Normal  Abnormal
     1. If Abnormal, specify:

1. Atrophy:  Present  Absent
   * 1. If Present, indicate location(s):

Frontoparietal  Temporal  Occipital  Cerebellum

1. Abnormal Enhancement:  Yes  No
   * 1. If Abnormal, indicate location(s):

Cortex  White matter  Basal ganglia  Thalamus  Brainstem  Cerebellum

1. Eye abnormalities:  Yes  No
   1. If YES, specify:

Optic nerve abnormalities

Microphthalmia

Cataract

Other, specify:

Recorder Signature: Date:

## General Instructions

This form contains data elements that are collected for head computed tomography. Responses to categories are obtained from health professionals performing the procedure.

Important note: All of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended for all mitochondrial disease clinical studies to collect).

Please see the Data Dictionary for element classifications.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Date/Date performed – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss.
* Multiple CTs performed – Answer, only if head CT was performed.
* Head CT date performed – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Head CT age of affected – This is recorded for each brain CT performed. This is a derived element based on Date of Birth and Visit Date.
* Slice thickness – Answer should be recorded in millimeters (mm).
* Slice orientation – Orientation of the axial slices (e.g., parallel to the OML, parallel to the hard palate, etc.)
* Contrast used – Choose one. If YES, record the name of the contrast agent and its dosage.