

Details on item collection

Unless stated differently in Table 1 or below, all core set items should at least be evaluated for absence/presence of the condition at the visit. In order to assess improvement/worsening of a condition, we recommend completing the binary information by quantifiable measures as stated below if possible.

Whenever a date is required, we suggest recording the date of the medically reported diagnosis.

Below, certain items are described in more detail in order to harmonize collection and increase data reliability. The table also provides information on collection modalities.

1. age	<ul style="list-style-type: none"> • <i>date of birth</i> needs to be converted to <i>year of birth</i> for anonymization
2. permanent partial visual loss / field defect / blindness / RAPD	<ul style="list-style-type: none"> • if present, specify: AION/CRAO/other
3. headache	<ul style="list-style-type: none"> • new-onset headache / headache of unknown character
4. scalp tenderness	<ul style="list-style-type: none"> • patient-reported tenderness on hair brushing or self-palpation
5. imaging evidence of cranial arteritis sonographic evidence	<ul style="list-style-type: none"> • “halo” and “compression” sign <ul style="list-style-type: none"> - <i>halo sign</i>: “homogenous, hypochoic wall thickening, well delineated towards the luminal side, visible both in longitudinal and transverse planes, most commonly concentric in transverse scans”^{1 2} - <i>compression sign</i> of temporal arteries: “The thickened arterial wall remains visible upon compression; the hypoechoic vasculitic vessel wall thickening contrasts with the mid-echogenic to hyperechogenic surrounding tissue”^{1 2} • if no imaging was performed, record that the parameter was <i>not assessed</i> • record <i>vessels affected, date of examination</i>
6. histological arteritis	<ul style="list-style-type: none"> • if no biopsy was performed, record that the parameter was <i>not assessed</i> • record <i>anatomical region, date of biopsy</i>
7. constitutional: fever/pyrexia symptoms	<ul style="list-style-type: none"> • body temperature of 38.3°C (101°F) or higher³
8. PMR	<ul style="list-style-type: none"> • inflammatory bilateral shoulder/hip pain and stiffness
9. peripheral pulses	<ul style="list-style-type: none"> • record <i>pulsation</i> quality in the following arteries: <i>carotid, axillary, brachial, radial, and femoral</i>
10. dilatation/aneurysm	<ul style="list-style-type: none"> • permanent localized dilation of an artery with an increase in diameter compared to the expected normal diameter of the artery in question⁴ • if no imaging was performed, record that the parameter was <i>not assessed</i> • record <i>vessels with evidence of dilatation/aneurysm, date of examination</i>
11. inflammatory wall thickening of cranial and extracranial arteries (axillary, aorta, other involved vessels)	<ul style="list-style-type: none"> • indicated by the following imaging findings described by Koster et al.⁵ <ul style="list-style-type: none"> - CT, MR: circumferential wall thickening, wall contrast uptake

<ul style="list-style-type: none"> - MR: wall oedema - US: halo sign (see above for definition) • if no imaging was performed, record that the parameter was <i>not assessed</i> • record <i>vessels with evidence of wall thickening, date of examination</i>
<p>12. stenosis</p> <ul style="list-style-type: none"> • hemodynamically relevant stenosis, e.g. indicated by Doppler examination showing turbulence and increased flow velocities¹ • if no imaging was performed, record that the parameter was <i>not assessed</i> • record <i>vessels with evidence of stenosis and estimate of degree (percent) of lumen narrowing, date of examination</i>
<p>13. patient's global assessment of disease activity</p> <ul style="list-style-type: none"> • numeric rating scale capturing global assessment of disease activity <i>attributable to GCA and today</i>
<p>14. evaluator's global assessment of disease activity</p> <ul style="list-style-type: none"> • numeric rating scale capturing global assessment of disease activity <i>attributable to GCA and today</i>
<p>15. TIA</p> <ul style="list-style-type: none"> • record whether imaging revealed <i>signs of vasculitis of supplying arteries</i> • record whether the item was assessed by <i>CT / PET-CT / MR / US</i>
<p>16. stroke</p> <ul style="list-style-type: none"> • record whether imaging revealed <i>signs of vasculitis of supplying arteries</i> • record whether the item was assessed by <i>CT / PET-CT / MR / US</i>
<p>17. arterial hypertension</p> <ul style="list-style-type: none"> • record whether patient was <i>treated for arterial hypertension</i> • ideally list current <i>antihypertensive medication including doses</i>
<p>18. diabetes mellitus</p> <ul style="list-style-type: none"> • record whether condition was present • ideally list current <i>antidiabetic medication including doses</i> • ideally record <i>HbA1c</i>
<p>19. osteoporosis</p> <ul style="list-style-type: none"> • record whether there was <i>radiological evidence of a fragility fracture</i> • record <i>BMD</i> determined by DXA or qCT including date the testing was performed (not older than 12 months) • ideally list current <i>anti-osteoporotic medication including doses</i>
<p>20. serious infection</p> <ul style="list-style-type: none"> • presence of an infection requiring hospitalization • ideally record grade as follows:⁶ <ul style="list-style-type: none"> - Grade 3: <i>intravenous antibiotic, antifungal, or antiviral intervention or hospitalization indicated OR radiologic or operative intervention indicated OR herpes zoster complicated by post-herpetic neuralgia or eye involvement</i> - Grade 4: <i>life-threatening consequences – urgent intervention indicated</i> - Grade 5: <i>death from infection</i>
<p>21. other serious event</p> <ul style="list-style-type: none"> • defined by the FDA as <i>life-threatening, requiring hospitalization, causing disability/permanent damage, requiring intervention to prevent permanent impairment/damage</i>

<p>22. glucocorticoids: current use</p> <ul style="list-style-type: none"> record current dose as <i>mg per day prednisone equivalent</i> record <i>route of administration</i>
<p>23. glucocorticoids: recent use</p> <ul style="list-style-type: none"> presence of continuous intake over more than the last three months
<p>24. immunosuppressants/-modulators</p> <ul style="list-style-type: none"> <i>current medication</i> collect the following information: <i>drug (generic name), start date, dose, route of administration</i>; if applicable: <i>stop date, stop reason (inefficacy / AE / both / other)</i> <i>historical treatment</i> only record at baseline: <i>list previous drugs (generic name)</i>
<p>25. antiplatelet agents</p> <ul style="list-style-type: none"> <i>current medication</i> collect the following information: <i>drug (generic name), start date, dose, route of administration</i>; if applicable: <i>stop date, stop reason (inefficacy / AE / both / other)</i> <i>historical treatment</i> only record at baseline: <i>list previous drugs (generic name)</i>

AION, anterior ischaemic optic neuropathy; BMD, bone mineral density; CRAO, central retinal artery occlusion; CT, computed tomography scan; DXA, dual-energy x-ray absorptiometry; FDA, Food and Drug Administration; MR, magnetic resonance imaging; PET-CT, positron emission tomography computed tomography scan; PMR, polymyalgia rheumatica; qCT, quantitative computed tomography; RAPD, relative afferent pupillary defect; TIA, transient ischaemic attack; US, ultrasound.

Collection intervals

Generally, we recommend recording clinically relevant changes/events whenever they occur (e.g. new medication, imaging finding, osteoporotic fracture.) To provide guidance for routine collection, we suggest the following collection intervals.

<p>We recommend the following items to be reported with date if they occur:</p> <ul style="list-style-type: none"> death TIA stroke myocardial infarction infection malignancy other serious event
<p>We recommend recording the following items every 3-6 months:</p> <ul style="list-style-type: none"> Demographics <ul style="list-style-type: none"> weight smoking Symptoms <ul style="list-style-type: none"> ocular involvement headache scalp tenderness jaw claudication constitutional: fever/pyrexia symptoms polymyalgic symptoms

<ul style="list-style-type: none"> - Physical findings <ul style="list-style-type: none"> • cranial artery abnormality: cord-like thickening / nodularity / tenderness / reduced pulse and/or pulselessness • peripheral pulses • blood pressure - Laboratory tests <ul style="list-style-type: none"> • ESR • CRP • haemoglobin - Global assessment of disease activity - Comorbidities <ul style="list-style-type: none"> • arterial hypertension • diabetes mellitus - Treatment <ul style="list-style-type: none"> • glucocorticoids • immunosuppressants/-modulators • antiplatelet agents
We recommend recording the following items every 6-12 months:
<ul style="list-style-type: none"> - sonographic evidence of arteritis - dilatation/aneurysm - wall thickening - stenosis
We recommend recording the following items annually:
<ul style="list-style-type: none"> - height
For the following we recommend performing testing if indicated:
<ul style="list-style-type: none"> - BMD

1. Chrysidis S, Duftner C, Dejaco C, et al. Definitions and reliability assessment of elementary ultrasound lesions in giant cell arteritis: a study from the OMERACT Large Vessel Vasculitis Ultrasound Working Group. *RMD open* 2018;4(1):e000598. doi: 10.1136/rmdopen-2017-000598 [published Online First: 2018/06/05]
2. Schafer VS, Chrysidis S, Dejaco C, et al. Assessing Vasculitis in Giant Cell Arteritis by Ultrasound: Results of OMERACT Patient-based Reliability Exercises. *The Journal of rheumatology* 2018;45(9):1289-95. doi: 10.3899/jrheum.171428 [published Online First: 2018/07/03]
3. O'Grady NP, Barie PS, Bartlett JG, et al. Guidelines for evaluation of new fever in critically ill adult patients: 2008 update from the American College of Critical Care Medicine and the Infectious Diseases Society of America. *Critical care medicine* 2008;36(4):1330-49. doi: 10.1097/CCM.0b013e318169eda9 [published Online First: 2008/04/02]
4. Johnston KW, Rutherford RB, Tilson MD, et al. Suggested standards for reporting on arterial aneurysms. Subcommittee on Reporting Standards for Arterial Aneurysms, Ad Hoc Committee on Reporting Standards, Society for Vascular Surgery and North American Chapter, International Society for Cardiovascular Surgery. *Journal of vascular surgery* 1991;13(3):452-8. [published Online First: 1991/03/01]
5. Koster MJ, Matteson EL, Warrington KJ. Large-vessel giant cell arteritis: diagnosis, monitoring and management. *Rheumatology (Oxford, England)* 2018;57(suppl_2):ii32-ii42. doi: 10.1093/rheumatology/kex424 [published Online First: 2018/07/10]
6. Miloslavsky EM, Naden RP, Bijlsma JW, et al. Development of a Glucocorticoid Toxicity Index (GTI) using multicriteria decision analysis. *Annals of the rheumatic diseases* 2017;76(3):543-46. doi: 10.1136/annrheumdis-2016-210002 [published Online First: 2016/07/31]