



**Chronic Airways Assessment Test**

**CAAT™ (CAT™ renamed)**

**User Guide**

Expert guidance on frequently asked questions

Issue 8: November 2024

The **Chronic Airways Assessment Test (CAAT)** is the same questionnaire as the COPD Assessment Test CAT (CAT)<sup>™</sup>, with an adaptation of the introductory sentence referring to “your lung disease” instead of COPD to permit its application to other conditions. Note: It can be pronounced the same way as “CAT”.

Psychometric validation of CAAT in patients with asthma, asthma+COPD and COPD was performed using data from the NOVELTY study<sup>6,23</sup> and validation in non-cystic fibrosis bronchiectasis was initiated in 2024.

**The COPD Assessment Test (CAT)** is a patient-completed instrument that can quantify the impact of COPD on the patient’s health. It complemented existing approaches to assessing COPD, such as FEV1 measurement. It was initially designed, using a rigorous scientific development process, to provide a simple and reliable measure of health status in COPD to aid assessment of patients and promote communication between patients and clinicians. Validation studies conducted during the development of CAT and in the years since it was launched in 2009 have shown that it has properties very similar to more complex health status questionnaires such as the St George’s Respiratory Questionnaire (SGRQ)<sup>1</sup>. A systematic review<sup>2</sup> confirmed that the CAT provides reliable measurement of health status and is responsive to change with treatment and exacerbations. Since 2013 it has been incorporated as the preferred measure of symptomatic impact of COPD into clinical assessment schemes and is also included in the COPD Foundation Pocket Consultant guide. The CAT has been used for a number of purposes, including

- As a tool that helps patients and providers have a meaningful conversation when discussing the disease.
- To provide clinicians with a guide as to when to use maintenance treatment in COPD – as in the GOLD strategy document.
- By researchers in observational and interventional clinical studies to evaluate treatments and management strategies.
- In studies in people with asthma, bronchiectasis, and interstitial lung disease (ILD), although without formal validation of its use in those conditions.

The information in this guide is accompanied by some frequently asked questions in order to make it accessible and applicable to both clinical practice and research.

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On behalf of the CAAT Governance Board, November 2024

## **Section 1: Background, Terms of Use and Translations**

### ***What is the CAT and why was it developed?***

The CAT is a validated, short (8-item) patient-completed questionnaire, with good discriminant properties, developed for use in routine clinical practice and research to measure the health status of patients with COPD<sup>1</sup>. Despite the small number of component items, it covers a broad range of effects of COPD on patients' health. Studies have shown that it is responsive to change in a patient's health status and to treatment.<sup>2,3,4</sup> CAT was developed to address the need for a simple-to-use tool which can measure the effect of COPD on the patient's health and enhance understanding between patients and physicians of the disease's impact and help manage patients optimally to reduce the burden of disease. Additional information on the development of the CAT is included in Appendix 1.

### ***Why was the CAT modified to become the CAAT?***

Several studies demonstrated the potential of the CAT in respiratory indications other than COPD including asthma<sup>6</sup>, non-CF bronchiectasis<sup>7,8,9</sup> and ILD<sup>26,28</sup>, but the introductory sentence, which asked about the effect of COPD, was inappropriate for patients with other diseases.

### ***What is the CAAT?***

Its purpose is the same as the CAT - to measure the impact of the patient's disease on their health status or health-related quality of life. It consists of the same 8 questions as the CAT, but with a small modification to make it usable by patients with diseases other than COPD by changing the phrase "your COPD" in the introductory sentence to "your lung disease", and by changing the title from "COPD Assessment Test" to "Chronic Airways Assessment Test". (Note: CAAT can still be pronounced the same way as "CAT"), except in situations where this would be ambiguous (when using both CAT and CAAT) . Scoring of the CAAT is the same as for CAT and will be referred to as the CAAT score.

A recent detailed psychometric validation of CAAT using data from the NOVELTY study showed that is a valid measure in both asthma and COPD <sup>23</sup>. Whilst asthma patients

and COPD patients respond slightly differently to some items, the overall CAAT scores in asthma showed that it reflects the impact of the disease on a patient's health status in the same way as in COPD. There are currently multiple translations of the CAAT available and validation in COPD and asthma in the NOVELTY study was conducted in 19 countries<sup>6</sup>.

### ***Who funded the development and validation of the CAT and CAAT?***

CAT development was commissioned and funded by GSK.

The CAAT validation study in NOVELTY was commissioned and funded by AstraZeneca.

Ongoing validation in non-CF bronchiectasis is funded by AstraZeneca, Boehringer Ingelheim and GSK.

### ***How are the CAT and CAAT governed?***

The use and further development of both the CAT and CAAT is overseen by a Governance Board, which lies within the Global Allergy and Airways Patient Platform (GAAPP), a not-for-profit patient organization that is based in Vienna, Austria and represents over 150 global patient advocacy groups. The Board has a working group structure and is chaired by a representative of GAAPP.

#### Members of the Governance Board include:

Chairs of the Science Committees of GOLD and GINA

Patient advocacy representatives

Global clinical users and researchers in academia and industry

Scientific advisers with expertise in patient-reported outcomes

Current Membership of the CAAT Governance Board and its Clinical and Scientific Advisory Panel can be found on the GAAPP website ([link](#))

### ***What is the CAAT Governance accountable for?***

- Maximizing the value of the CAAT and CAT by promoting uptake and usage for clinical practice and research.
- Maintaining the integrity of CAAT and CAT by developing and approving translations.

- The oversight of both the CAAT and its predecessor CAT in terms of materials, platforms and additional development.
- Updating the CAAT User Guide and Implementation Guide for health care professionals on how to use and interpret CAT and CAAT scores in the form of a user manual available through the GAAPP website ([link](#)).

**Terms of use of the CAAT:**

The CAAT should be used **without changes**. Multiple translations are available on the GAAPP website ([link](#)). The CAAT form text cannot be altered as it is protected by Copyright<sup>25</sup>.

Publications should use the following copyright statement:

**” The COPD assessment test (CAT) and the Chronic Airways Test (CAAT) were developed by an interdisciplinary group of international experts with support from GSK. CAT and CAAT activities are monitored by a supervisory council that includes independent experts, one of which is chair of the council. CAT, COPD Assessment Test, CAAT, Chronic Airways Assessment Test and the CAT logo are trademarks of the GSK group of companies. ©2009-2024 GSK 'Group of Companies' or its licensor. All rights reserved”**

- **Terms of use of the CAAT in clinical practice**

The CAT and CAAT are free to use in clinical practice. CAAT forms and translations are available on the CAAT website (<https://gaapp.org/caat-cat/>). GAAPP will get any necessary translations (email [CAAT@GAAPP.Org](mailto:CAAT@GAAPP.Org)).

- **Terms of use of CAAT in academic studies (interventional and observational)**

Clinical and academic users can use CAAT for audit and research purposes without prior permission from CAAT Governance Board, this includes studies that are funded by government or charitable organizations (for implementation support or to request translations email [CAAT@GAAPP.org](mailto:CAAT@GAAPP.org))

- **Terms of use of the CAAT for “for profit” Industry-sponsored studies (interventional and observational)**

Sponsored for profit Industry research users are required to complete a request for use with [Mapi Research Trust](#) eProvide platform (MRT). Mapi will provide sponsors with

translations and translation certificates. Mapi charge for this service; for observational research studies, Mapi may consider reduced charges with GSK the IP owner.

- Register on the MRT platform or log in. Click on the dark blue “Submit a Request” button on the ribbon at the top right of the page.
- There is no cost to submit a request for use.
- Enter required details and someone from MRT will contact you within 3 business days to arrange a license agreement.

**Note:** When using the CAT in a Regulatory submission in the US, please refer to A Drug Master File Type V (DMF #32316) containing compiled data on CAT that has been submitted by the COPD Foundation to the FDA<sup>21</sup> and can be referenced by interested companies by contacting [CAAT@GAAPP.org](mailto:CAAT@GAAPP.org).

- ***Terms of use for integration into Electronic Medical Record Systems***

The systematic inclusion of CAT or CAAT in an electronic medical record by a hospital or other health organization is possible. The CAAT form text cannot be altered<sup>25</sup> and integration should follow the [Digital Implementation Guide](#) and request Permission to Use through the Governance Board who will review screenshots to ensure they adhere to GSK (the copyright owner) and Governance Board guidelines. The role of GSK and the CAAT Governance Board must be acknowledged using the IP statement above. If any change to the CAT or CAAT layout is made, guidance should be sought via the CAAT Governance Board for guidance ([CAAT@GAAPP.org](mailto:CAAT@GAAPP.org)).

### ***Translations of the CAAT***

The CAAT/CAT is used as a Patient Reported Outcome measure (PRO). It is therefore important that new translations are linguistically validated to the highest standards. Internationally recognized processes for translation<sup>22</sup> are required for all new translations which are commissioned.

The CAAT and its available translations formatted for printing can be found on the [GAAPP](#) website for personal use, academic research and clinical practice. The GB aim to support the global community and can obtain additional translations as needed.

Only approved translations of the CAT and CAAT questionnaires should be used to ensure the validity and measurement properties of the questionnaire are maintained. For additional translations missing on the website, email [CAAT@gaapp.org](mailto:CAAT@gaapp.org)

For other “for profit sponsored studies” contact [Mapi Research Trust as noted in terms of use](#). **It is not a requirement that new translations be developed via GAAPP or Mapi Trust.**

New certified translations and certificates will be shared with the community if sent to [CAAT@GAAPP.org](mailto:CAAT@GAAPP.org).

Note: A webpage for electronic CAAT and translations will be developed in the future.

## **Section 2: Using the CAAT or CAT in Routine Clinical Practice**

### ***Why should I use the CAAT or CAT?***

The CAAT and CAT are near-identical short, simple questionnaires which are quick and easy for patients to complete. Each questionnaire provides a framework for discussions with patients to enable patient and clinician to gain a common understanding and grading of the impact of the condition on their life. It should also help identify where disease has the greatest effect on the patient's health and daily life.

**We recommend transitioning to using the CAAT** to maximize the value of the tool beyond its application as the CAT in COPD.

### ***Where and how does the CAAT fit into the clinical assessment of COPD or asthma?***

The CAT provides a reliable measure of the impact of COPD on a patient's health status<sup>1,2</sup> and provides supplementary information to other clinical assessments of the severity of COPD, for example exacerbation risk and FEV<sub>1</sub><sup>8</sup>.

The role of the CAAT in routine assessment of asthma has yet to be established, for example choice of threshold scores for changes in the patient's treatment, but in principle it should provide a similar role in assessment of the impact of asthma on a patient's health status.

### ***For which patients is the CAAT suitable?***

The CAAT is suitable for completion by all adults diagnosed with COPD, asthma and adults with both asthma and COPD. Additional validation is needed for patients with other diseases; validation in non-CF bronchiectasis was initiated in 2024.

### ***Can the CAAT be used in all patients irrespective of disease severity?***

Yes. The CAT was developed and validated in COPD patients aged 40 and above of all severities and the first validation of the CAAT in asthma was also performed in patients with mild to severe disease. For CAT, stable patients of all COPD severities (defined by FEV<sub>1</sub>) and exacerbating patients were included in the development population,<sup>1,3, 6</sup> but CAAT has not yet been evaluated in patients with exacerbations of asthma.



***Can the CAAT replace spirometry?***

No. The CAAT and spirometry are complementary measures which should be used together in the clinical assessment of a patient's COPD or asthma. Spirometry is essential for the diagnosis of COPD.

***Can I use the CAAT to diagnose COPD or asthma?***

No, the CAAT is not a diagnostic tool and it cannot be used as one. It has, however been used to assess health status and as an entry criterion in COPD and NCFB clinical trials.

***Can the CAAT help me make management decisions regarding any co-morbidities which my patients with lung disease may also have?***

No. The CAAT is a disease-specific tool to measure the impact of COPD or asthma on patients. It will not provide an assessment of co-morbid conditions or provide information to help guide any management decisions for co-morbid conditions.

***How does the CAAT compare with other health status measures used in asthma or COPD?***

The CAAT has similar discriminative properties to the SGRQ which is often used in clinical trials<sup>1</sup>, however, the CAAT is much simpler and quicker to complete. The relative sensitivity of these two instruments to treatment effects has yet to be established, but the CAAT has the advantage that its scores may be more readily translated into clinical practice.

## **Section 3: Practical Advice on Using the CAAT or CAT**

### ***Which questionnaire should I use in COPD – CAT or CAAT?***

For clinical and academic users, transitioning to using the CAAT in COPD is recommended. For existing COPD studies using CAT, it is recommended that this should be continued until the end of the study, and for new studies in asthma and/or COPD, it is recommended that CAAT should be used. However, for pharmaceutical and medical device users who are conducting COPD studies, it is recommended the CAT should continue to be used until there is a clear indication from regulatory authorities about the CAAT.

### ***When do I give the CAAT (or CAT) to my patients to complete?***

It is recommended that a patient is asked to complete a CAAT (or CAT) when they arrive for a check-up appointment or immediately before attending. Patients can download the CAAT or use a printed form and complete it while waiting in the clinic or at home prior to consultation.

### ***Do patients require much instruction to complete the CAAT or CAT?***

The CAAT and CAT both contain guidance to the patient about completing the questionnaire and it is preferred that they complete them independently, but discussion between patient and carer may be appropriate, the clinician should be aware that this has taken place.

### ***What is the scoring range of the CAT and CAAT?***

The CAAT/CAT have a scoring range of 0-40.

### ***What do CAT/CAAT scores mean?***

The implication of the scores needs to be considered in relation to an individual's disease severity. For the CAT the following have been suggested for grading the severity of the impact of COPD on the patient's health

Low <10

Medium 11-20

High 21-30

Very high >30

The psychometric validation of the CAAT shows that it measures the same construct in both asthma and COPD, so these broad grading systems should still apply, but they should not be used to determine changes in treatment until validated for this purpose.

***How frequently should the CAAT or CAT be used in patients?***

The Governance Board and the GOLD strategic document recommend that patients routinely complete the CAAT/CAT questionnaire every 2 to 3 months to detect changes and trends in CAAT/CAT score<sup>12</sup>. The Governance Board recommends a similar approach in other indications.

***What change in CAAT or CAT score is meaningful?***

A difference or change of 2 or more units over 2 to 3 months suggests a clinically important difference or change in health status. Research has been published to define ranges of CAT score severity and to understand the minimal clinically relevant change (often referred to as the Minimum Clinically Important Difference or MCID) in a CAT score from one visit to the next<sup>3,4,15</sup>. A similar MCID may be appropriate in CAAT or other indications, but additional validation is required.

***Can CAAT be used to set a target score?***

In COPD, ideally a target score of <10 should be set, but that needs to set into the context of treatment risk-benefit, feasibility in a progressive disease and availability.

In asthma, a target Asthma Control Test Score (ACT) score >20 (well-controlled asthma) is sometimes recommended, but no similar threshold has yet been established for CAAT.

***What if my patient's CAAT or CAT score gets worse?***

Based on the correlation with SGRQ the CAAT/CAT score would not be expected to decrease by more than 1 unit per year (on average)<sup>14</sup> but some patients do worsen more quickly<sup>26,27</sup>.

Worsening scores may indicate that patients are experiencing exacerbations that they have not reported, or a new (or worsening) comorbidity is contributing to poor health status. Scores may also worsen when a patient has stopped or is not taking their treatment

effectively. Inhaler technique and adherence to treatment should be checked. Where rapid disease progression is suspected, referral for specialist opinion is suggested.

In addition, for each scenario, the CAT Development Steering Group proposed some potential management considerations<sup>17</sup>:

Recommendations for the CAAT are an ongoing effort by the Governance Board and will be published in due course.

***What are the clinical implications of different CAT scores in COPD?***

<b>CAT score</b>	<b>Impact level</b>	<b>Broad clinical picture of the impact of COPD by CAT score</b>	<b>Possible management considerations</b>
>30	Very high	<p>Their condition stops them doing everything they want to do and they never have any good days. If they can manage to take a bath or shower, it takes them a long time. They cannot go out of the house for shopping or recreation, or do their housework.</p> <p>Often, they cannot go far from their bed or chair. They feel as if they have become an invalid.</p>	<p>Patient has significant room for improvement</p> <p>In addition to the guidance for patients with low and medium impact CAT scores consider:</p> <ul style="list-style-type: none"> <li>• Referral to specialist care (if you are a primary care physician)</li> </ul> <p>Also consider:</p> <ul style="list-style-type: none"> <li>• Additional pharmacological</li> </ul>

>20	High	<p>COPD stops them doing most things that they want to do. They are breathless walking around the home and when getting washed or dressed. They may be breathless when they talk. Their cough makes them tired and their chest symptoms disturb their sleep on most nights. They feel that exercise is not safe for them and everything they do seems too much effort. They are afraid and panic and do not feel in control of their chest problem.</p>	<p>treatments</p> <ul style="list-style-type: none"> <li>• Referral for pulmonary rehabilitation</li> <li>• Ensuring best approaches to minimizing and managing exacerbations</li> </ul>
10-20	Medium	<p>COPD is one of the most important problems that they have. They have a few good days a week but cough up sputum on most days and have one or two exacerbations a year. They are breathless on most days and usually wake up with chest tightness or wheeze. They get breathless on bending over and can only walk up a flight of stairs slowly. They either do their housework slowly or have to stop for rests.</p>	<p>Patient has room for improvement – optimize management.</p> <p>In addition to the guidance provided for patients with low impact CAT scores consider:</p> <ul style="list-style-type: none"> <li>• Reviewing maintenance therapy – is it optimal?</li> <li>• Referral for pulmonary rehabilitation</li> <li>• Ensuring best approaches to minimizing and managing exacerbations</li> <li>• Reviewing aggravating factors – is the patient still smoking?</li> </ul>

<10	Low	<p>Most days are good, but COPD causes a few problems and stops people doing one or two things that they would like to do. They usually cough several days a week and get breathless when playing sports and games and when carrying heavy loads. They have to slow down or stop when walking up hills or if they hurry when walking on level ground. They get exhausted easily.</p>	<ul style="list-style-type: none"> <li>• Smoking cessation</li> <li>• Annual influenza vaccination</li> <li>• Reduce exposure to exacerbation risk factors</li> <li>• Therapy as warranted by further clinical assessment.</li> </ul>
5		Upper limit of normal in healthy non- smokers	

### ***What effect does a COPD exacerbation have on CAT scores?***

CAT scores in patients with moderate- severe COPD exacerbations are approximately 5 units higher than in those who have stable COPD.<sup>1,3</sup> This finding is supported by subsequent research<sup>18</sup>. In patients responding to treatment for their exacerbation, the CAT score has been found to decrease by 2 units in 14 days, whilst patients who did not respond had no change in score<sup>3</sup>. A systematic review of research studies has also shown that it may take many weeks for patients to recover fully from a single moderate-severe exacerbation and some patients may never recover fully<sup>2</sup>. Therefore, another potential application of the CAT/CAAT may be to assess the degree of recovery following an acute exacerbation by re-assessing 2-3 months after the event.

### ***Can I assess response to therapy with the CAT/CAAT in clinical practice?***

The CAT has relatively good repeatability<sup>1,2</sup> and in a study of patients undergoing rehabilitation, CAT scores decreased by 3 units over 42 days in patients reporting an improvement in their COPD. In patients who reported worsening of COPD over the same period CAT scores increased by 2 units<sup>3</sup>. However, it's important to be aware that, like all patient reported outcomes, CAT/CAAT was designed to provide a standard measure suitable for *all patients* with the condition, not a specific *individual patient*. When assessing treatment response in an *individual patient* CAAT scores can be useful in combination with other measures, including the question: "Have you noticed a change since starting the treatment?"

Whilst this may be a limitation, there is good evidence that trends in CAT/CAAT score in individual patients can be detected through regular administration of the CAT, for example through telemonitoring<sup>27</sup>

### ***Can I just use a few of the questions included in the CAAT?***

No. The CAT should be used in its entirety. The CAT/CAAT was validated as an 8-item questionnaire and the questions should not be split up or used independently of each other as this would reduce the integrity and measurement properties of the questionnaire. However, responses to the individual items can be used to provide you with an indication of the areas of the patient's health that are more affected than others. For example, one patient may have higher scores for cough and sputum, whereas another may have highest scores for the items about activity or sleep.

## ***Section 4: Modes of Administration for the CAAT or CAT***

### ***Can the CAAT/CAT be used on electronic data collection devices?***

The CAT has been tested and used on a number of electronic data collection devices (electronic Clinical Outcomes Assessment or eCOA). Generally, existing evidence suggests that as long as only minor modifications were made to a PRO measure during the migration process the psychometric properties of the original measure will still hold for the eCOA version. Measurement equivalence of the two measures will still need to be demonstrated but the level of evidence required may be less than if more substantial changes are required. Migration of the CAT or CAAT to a new eCOA device should be conducted and evaluated using international guidelines<sup>19, 20</sup>. Further details are provided in the next section of this user guide.

### ***What if I want to develop and use a new ePRO adapted from the CAAT/CAT?***

Migration of the CAT or CAAT to a new eCOA platform or device needs to be supported by evidence to demonstrate the comparability, or measurement equivalence, of the ePRO to the paper-based CAT or CAAT. Important considerations about the level of evidence needed include a) the extent of modification required to administer the PRO on the eCOA device and b) how best to effectively test the measurement equivalence of the two modes of administration. Published reports and guidance are available which provide support and general frameworks for this development<sup>19</sup>

### ***Are there specific requirements for migrating CAAT or CAT to a new eCOA platform?***

When migrating CAAT/CAT to a new screen-based platform the horizontal format of the questions must be maintained, i.e.; the anchor statements should be located at each end of the response scale (not above or below the scale). Additional line breaks may be incorporated into each anchor statement. On e-diary devices it is acceptable to show one question per screen with the instructions on one or more introductory screens. For devices with larger screens multiple questions may be shown, In the ideal case the whole questionnaire should be presented to the patient however international requirements on text size and usability may prevent this.

Any incorporation of CAAT/CAT into a 'bring your own device' data collection method should take into account the screen sizes likely to be used in any study<sup>20</sup>.

Further information on the requirements for eCOA migration and formatting can be



obtained from [Mapi Reseach Trust](#) or the CAT/CAAT [implementation guide](#).

***What mode of administration was the CAT developed for?***

The CAAT/CAT was developed for patient self-complete mode of administration.

***Can the CAAT or CAT be administered via clinician/investigator interview?***

The CAT was developed for self-complete mode of administration and has not been tested for interviewer administration. As such we cannot confirm that the CAT will behave the same way as it would in self-complete mode of administration. If it is absolutely necessary to undertake interview administration (e.g., due to profound vision impairment), then the interviewer must endeavor to read the instructions, items, and responses in a neutral tone, adding emphasis only where indicated via the text.

**The patient's selected response should be repeated to him/her to confirm.**

***Can the CAT or CAAT be administered via caregiver interview?***

The CAT was developed for self-complete mode of administration and has not been tested for interviewer administration. **We do not support caregiver interview using the CAT or CAAT as it has yet to be studied**, but use of proxies has been shown to be reliable using the SGRQ<sup>24</sup>.

## ***Appendix 1: Additional information about CAT in COPD***

The CAT was developed by a multidisciplinary group of international experts that included pulmonary specialists, primary care physicians, experts in the development of patient reported outcome measures and representatives from patient advocacy organizations listed below using well accepted methodologies used for the development of psychometric tools.<sup>1,10</sup> Patients with COPD were integral to its development.

It was initially validated in prospective studies conducted in the USA and Europe<sup>1</sup> and China<sup>10</sup>. In the years since launch further validation studies have been conducted around the world which show that the CAT is globally applicable. Since 2009 the CAT has been translated and validated for use in more than 100 languages. Local validation studies have been conducted in countries that include China, Arabic-speaking countries, Brazil, Greece, Japan, South Korea, Turkey and Thailand. All have shown that it is reliable in those settings and that both patients and researchers find it easy to use. Note: Only validated translations of the CAT should be used<sup>25</sup>.

### **Acknowledging the Original CAT Development Steering Group**

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The COPD assessment test (CAT) and the Chronic Airways Test (CAAT) were developed by an interdisciplinary group of international experts with support from GSK. CAT and CAAT activities are monitored by a supervisory council that includes independent experts, one of which is chair of the council.

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