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Healthcare Professional User Guide

Expert guidance on frequently asked questions

Issue 4: November 2018

[Inside front cover]

Introducing the COPD Assessment Test™ (CAT)

The COPD Assessment Test (CAT) is a patient-completed instrument that can quantify the impact of COPD on the patient's health. It complements existing approaches to assessing COPD, such as FEV_1 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 much more complex health status questionnaires such as the St George's Respiratory Questionnaire (SGRQ)[1]. A recent systematic review[2] 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 guide.

Although it was developed in English nearly one hundred validated translations have been made and 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 the CAT is reliable in those setting and that both patients and researchers find it easy to use.

Since the launch of CAT, guidance has been provided for healthcare professionals on how to use and interpret CAT scores in the form of a user manual available through the website (www.catestonline.org). As it is increasingly used in research this update to the user manual has been expanded to include information and advice to both academic and commercial researchers, based upon our current knowledge of the CAT and its measurement properties.

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

We look forward to hearing and reading about your experiences using the CAT in the near future!

Professor Mike Polkey	*Professor Claus Vogelmeier*	*Professor Mark Dransfield*
Independent Chair	*GOLD Science Committee Chair*	*COPD Foundation Consortium Working Group Chair*

On behalf of the CAT Governance Board, November 2018

The COPD Assessment Test™ (CAT) – the basics

What is the CAT?
The CAT is a validated, short (8-item) and simple patient completed questionnaire, with good discriminant properties, developed for use in routine clinical practice to measure the health status of patients with COPD[1]. 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 and to treatment.[2,3,4]

Why has the CAT been developed?
COPD represents a major burden on patients and healthcare systems. Despite the fact that it is projected to become the third leading cause of death by 2030[5], communicating the impact of COPD can be difficult and this can contribute to under-management of COPD in a significant proportion of people who may suffer increased disability and reduced quality of life as a result.

The care of COPD patients can only be optimised if there is a reliable, standardised measure of the overall effect of disease on each patient's health. Unfortunately, commonly used lung function measurements such as FEV_1 percent predicted do not reflect the full impact of COPD.

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, in order to manage patients optimally and reduce the burden of disease as much as possible.

Development and Governance of the COPD Assessment Test™ (CAT)

How was the CAT developed?
The development of the CAT involved well accepted methodologies used to develop psychometric tools.[1,6] The initial item generation process involved literature reviews, physician interviews and, most importantly, patient input.[6] A structured, rigorous scientific approach was then used in the item reduction process to select the best items and generate the final 8-item questionnaire.[1]

The CAT was initially validated in prospective studies conducted in the USA and Europe[1] and in China[7]. 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 90 languages other than English. Only validated translations of the CAT should be used. You can gain access to these translations on the CAT website, www.CATestonline.org.

Who developed the CAT?

The CAT was developed by a multidisciplinary group of international experts who have expertise in developing patient reported outcomes tools/questionnaires. The group included pulmonary specialists, primary care physicians, experts in the development of Patient Reported Outcome measures and representatives from patient bodies (appendix 1). Patients with COPD were integral to the development and validation of the tool. The CAT development was commissioned and funded by GlaxoSmithKline (GSK).

How is the CAT governed?

Use and further development of the CAT is overseen by a Governance Board established in 2015. The board has an independent academic chair. GOLD and The COPD Foundation (COPDF) nominate and confirm representatives on the CAT Governance Board. GOLD is represented by the chair of the Science Committee and COPDF is represented by a member of the Board or a Consortium Working Group Chair. Other members of the Governance board represent research in industry and academia. The Board also includes a scientific adviser with expertise in the development and use of PRO. GSK continues to own the copyright for the CAT to ensure its integrity, maintains the CAT websites and is responsible for the administrative support of the CAT Governance Board in addition to making translations of the CAT available to users.

Who are members of the CAT Governance Board?

Current Membership of the CAT Governance Board (November 2018):

Independent Chair:	Professor Michael Polkey, NIHR Respiratory Biomedical Research Unit at the Royal Brompton and Harefield Foundation NHS Trust and Imperial College
GOLD Scientific Committee Chair:	Professor Claus Vogelmeier, Professor of Medicine and Chair Department of Medicine, Pulmonary and Critical Care Medicine, University Medical Center Giessen and Marburg, Philipps-University Marburg, Germany, Member of the German Center for Lung Research (DZL)
COPD Foundation Working Group Consortium Chair:	Professor Mark Dransfield Division of Pulmonary, Allergy and Critical Care Medicine University of Alabama at Birmingham
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Scientific Adviser:	Maggie Tabberer, Director, Patient Centred Outcomes, Value Evidence and Outcomes GSK
Foundation Chair:	Professor Paul Jones,

What does the CAT Governance Board do?

The CAT Governance Board is accountable for the oversight of CAT in terms of materials, platforms and developments. Key activities will include:

- Maximising the value of CAT by promoting uptake and usage as widely as possible and ensuring adoption of new terms of use
- Maintaining the integrity of CAT by developing and approving translations available via the website
- Expanding the use of the CAT in clinical practice and in research

The Governance Board will also contribute to the Regulatory qualification efforts of the CAT as a drug development tool by the COPD Foundation Biomarker Qualification Consortium.

How does the Governance Board regulate the use of the CAT?

GSK and the CAT Governance Board have decided that the CAT is free to use in clinical practice and in research within the terms of use there are set out on the CAT website (www. CATestonline.org). Please review these terms to ensure that your proposed use of the CAT is covered. Certain research uses require that you complete an on-line application form on the CAT website If your proposed use of the CAT is not covered by the terms of use, please contact GSK as set out on the CAT website with your proposal and GSK will consider the proposal with the CAT Governance Board on a case-by-case basis having regard to the aims set out above.

Why does GSK hold the copyright for CAT?

GSK continues to hold copyright to ensure that translations of the CAT are conducted appropriately and are collected and made available to clinicians and researchers. Translations of the CAT have been approved by the CAT Governance Board and are available from the website.

GSK also provides administrative support to the Governance Board. In all activities related to the CAT, GSK will be guided by the advice and direction given by the CAT Governance Board. To get valid results from the CAT all eight questions must be used, in the order they are presented on the website.

Using the CAT in everyday clinical practice: why, who and when?

Why should I use the CAT?

The CAT is a short, simple questionnaire which is quick and easy for patients to complete. It provides a framework for discussions with your COPD patients and should enable you and them to gain a common understanding and grading of the impact of the disease on their life. It should also help you to identify where COPD has the greatest

effect on the patient's health and daily life. As a result you may be better informed when discussing and making management decisions with your patients and be able to ensure that his or her health status is as good as it can be.

Where and how does the CAT fit into the clinical assessment of COPD?
The CAT provides a reliable measure of the impact of COPD on a patient's health status.[1,2] It therefore provides supplementary information to that provided by other aspects of COPD clinical assessment recommended by current management guidelines (i.e. assessment of exacerbation risk and degree of airway obstruction, assessed using spirometry)[8].

The CAT does not replace COPD treatments but can help you monitor their effects, e.g. rehabilitation programmes or recovery from an exacerbation[4,10,11].

For which patients is the CAT suitable?
The CAT is suitable for completion by all patients diagnosed with COPD.

Can the CAT be used in all COPD patients irrespective of disease severity?
Yes. The CAT has been developed and validated in COPD patients of all severities. Stable patients of all severities (defined by FEV1) and exacerbating patients were included in the development population [1,3, 6]

Does the CAT replace spirometry?
No. The CAT is not a diagnostic tool. Spirometry is essential for the diagnosis of COPD. The CAT and spirometry are complementary measures which can be used together in the clinical assessment of a patient's COPD to ensure that they are being optimally managed.

Can I use the CAT to diagnose COPD?
No, the CAT cannot be used alone as a diagnostic tool. Although the CAT is a scientifically developed tool for measurement of health status it is not a diagnostic instrument, unlike measures of lung function such as FEV_1, which confirm the diagnosis of COPD and assess the degree of airway obstruction.

Will the CAT help me make management decisions regarding any co-morbidities which my COPD patients may also have?
No. The CAT is a disease-specific tool to measure the impact of COPD 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 CAT compare with other health status measures used in COPD?
The CAT has very similar discriminative properties to the much more complex SGRQ which is often used in clinical trials showing that it will be able to measure the impact of COPD on individual patient's health[1]. However, the CAT is much simpler and quicker to complete. This similarity enables us to describe what a patient's CAT score may mean and, more importantly, to interpret changes in CAT score.

Practical use of the CAT

When do I give the CAT to my patients to complete?
It is recommended that you ask a COPD patient to complete a CAT questionnaire when they arrive for a check-up appointment for their COPD or immediately before attending. The CAT test can also be completed online via the CAT website and printed out or emailed directly to you and takes only a couple of minutes. Patients could

complete it whilst waiting to see you or at home prior to consultation. The completed CAT questionnaire can then provide a framework for your consultation.

Where can I access the CAT questionnaire?
You can download the CAT questionnaire from www.CATestonline.org

Will patients require much instruction to complete the CAT?
The content of the CAT questionnaire has been driven by COPD patients. It comprises 8 simple questions that most patients should be able to understand and answer easily. You should not need to assist patients to complete it. In fact it is much better if they complete this independently.

What is the scoring range of the CAT?
The CAT has a scoring range of 0-40.

What do CAT scores mean?
The implication of the CAT scores needs to be considered in relation to an individual's disease severity. Several studies have indicated that the relationship between lung function (FEV1) and health status scores is generally weak[9,12]. As recognised by the GOLD strategic document the lung function, exacerbation frequency and health status are complementary[8] and all together help to define the severity of the disease in a particular patient.

How frequently should the CAT be used in patients?
The CAT Governance Board and the GOLD strategic document recommend that patients routinely complete the CAT questionnaire every 2 to 3 months to detect changes and trends in CAT score[8].

What change in CAT score is meaningful?
A difference or change of 2 or more units over 2 to 3 months in a patient suggests a clinically significant 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[3,4,11].

Can CAT be used to set a target score?
Since COPD is a progressive disease, a fixed target score for all patients cannot be set. In Practice, a target for improvement in individual patient CAT scores may be set, based on an holistic assessment of the patient. A change of 2 units suggests a meaningful difference.

What if my patient's CAT score gets worse?
Based on the correlation with SGRQ the CAT score would not be expected to decrease by more than 1 unit per year[10]. Worsening scores may indicate that patients are experiencing exacerbations that they have not reported to you. CAT scores may also worsen where a patient has stopped or is not taking their treatment effectively. Check inhaler technique as well as adherence to treatment. Where rapid disease progression is suspected, referral for specialist opinion may be required.

In addition, for each scenario, the CAT Development Steering Group proposed some potential management considerations[13]:

CAT score	Impact level	Broad clinical picture of the impact of COPD by CAT score	Possible management considerations
>30	Very high	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. Often, they cannot go far from their bed or chair. They feel as if they have become an invalid.	Patient has significant room for improvement In addition to the guidance for patients with low and medium impact CAT scores consider: • Referral to specialist care (if you are a primary care physician) Also consider: • Additional pharmacological treatments • Referral for pulmonary rehabilitation • Ensuring best approaches to minimising and managing exacerbations
>20	High	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.	
10-20	Medium	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.	Patient has room for improvement – optimise management In addition to the guidance provided for patients with low impact CAT scores consider: • Reviewing maintenance therapy – is it optimal? • Referral for pulmonary rehabilitation • Ensuring best approaches to minimising and managing exacerbations • Reviewing aggravating factors – is the patient still smoking?
<10	Low	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.	• Smoking cessation • Annual influenza vaccination • Reduce exposure to exacerbation risk factors • Therapy as warranted by further clinical assessment.
5		Upper limit of normal in healthy non-smokers	

What effect does an exacerbation have on CAT scores?
We know from the first CAT validation study that CAT scores in patients with moderate-severe exacerbations are approximately 5 units higher than in those who have stable COPD.[1,3] This finding is supported by subsequent research[14]. Patients responding to treatment for their exacerbation have been shown to reduce their CAT score by 2 units in 14 days, whilst patients who did not respond had no change in score [3]. A systematic review of research studies have 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[2]. Therefore another potential application of the CAT may be to assess the degree of recovery following an acute exacerbation by re-assessing the CAT score 2-3 months after the event.

Will I be able assess response to therapy with the CAT?
We know that the CAT has good repeatability[1,2], which is similar to that for the FEV_1 and, based upon our current knowledge, we believe that the relative size of its response to therapy will also be similar to that of the FEV_1. 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[3]. In assessing whether an *individual patient* has had a worthwhile response to a specific therapy, a thorough individual assessment taking a number of factors into account – including change in CAT score - will be required. However, the CAT *will* provide a measure of the individual patient's health that will be very useful in initial assessment and for following medium to long-term trends. It should also provide a prognostic measure of future health resource use in *individual patients*. The design of the CAT may also allow clinicians to readily identify areas of a patient's health that are more severely impaired than others, such as mood, daytime physical function or sleep.

Can I just use a few of the questions included in the CAT?
No. The CAT should be used in its entirety. The CAT was validated as an 8-item questionnaire and the questions should not be split up or used independently of each other which will 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.

Is the CAT free to use?
Yes. The CAT is available and free to use globally (no charges will be associated with its use) in the situations described in the terms of use on the CAT website.

Do I need permission to use the CAT?
The CAT can be used in clinical practice without permission, as long as you respect the integrity of the test. To use the CAT in research you will need to agree to the terms and conditions of use which appear on the CAT website (www.CATestonline.org). All copyright information must be maintained as they appear on the bottom of the CAT questionnaire. Details of how to access the CAT for use in research are given in the next sections of this User Guide.

Is the CAT available in different languages?
Yes. The CAT is available in more than 90 different languages. Only approved translations of the CAT questionnaire should be used to ensure the validity and measurement properties of the questionnaire are maintained. For further details on validated translations please visit www.CATestonline.org.

Systematic Use of the CAT

Can I include the CAT routinely in health records in Clinical Practice?
Yes. The CAT was developed to help health care professionals monitor the health status of their patients with COPD so recording CAT scores in the patients medical record assists this process and is encouraged.

Can I include the CAT in my Hospital Electronic Medical Record System?
The systematic inclusion of CAT in an electronic medical record by a hospital or other health organisation is possible. If the CAT is to be completed by the patient then it must be laid out in accordance with the terms of use and acknowledge the role of GSK, the CAT steering committee and the CAT Governance Board must be acknolwleded. If any change to the CAT layout is made guidance should be sought (link to contact us).

Using the CAT in Research

During the development of the CAT it became apparent that the measurement properties and responsiveness of the instrument were very similar to those of the more complex and longer SGRQ[1]. This relationship has been demonstrated further in a number of studies[2]. A formal mapping exercise was carried out which described the relationship and constructed a 'ladder' of COPD disease impact at different cut-off points of CAT score (Table 1: Jones, Tabberer, Chen 2011).

Furthermore, following extensive translation and linguistic validation the measurement properties and responsiveness of the CAT have been evaluated in many different countries and found to be similar[2].

The primary focus of the CAT Governance Board initially is to maximise the use and value of the CAT for patients, healthcare professionals and researchers. The information in the next sections of this guide will help you to use the CAT productively in research.

Do I need a licence to use the CAT in research?

There is no licence fee associated with the use of the CAT. However the CAT must be used within certain terms and conditions which must be agreed to before translations of the CAT will be made available. Terms of use and translations are available on the CAT website (www.CATestonline.org)

How do I get permission to use the CAT?

You will need to apply through the website for permission to use CAT. This permission is automatically generated when you request translations. Most journals will need to see this permission when you submit your study for publication. You will find it helpful to formalise your permission to use the CAT for all studies using the 'log study and request translations' part of the website

How do I obtain translations for my study?

You can obtain multiple translations and supporting certificates from the research area of the CAT website. You will need to provide register your study and provide contact details (name, afilliation and e-mail) and some details of your proposed study and

agree to the terms and conditions of use of the CAT before accessing the translations. A schematic of the process is shown in figure 1.

What happens if the language I need is not available?

If the language you require is not available you will be able to request information about availability through the translation order form. We will be able to let you know if the language you need is already in development or if a new translation is needed.

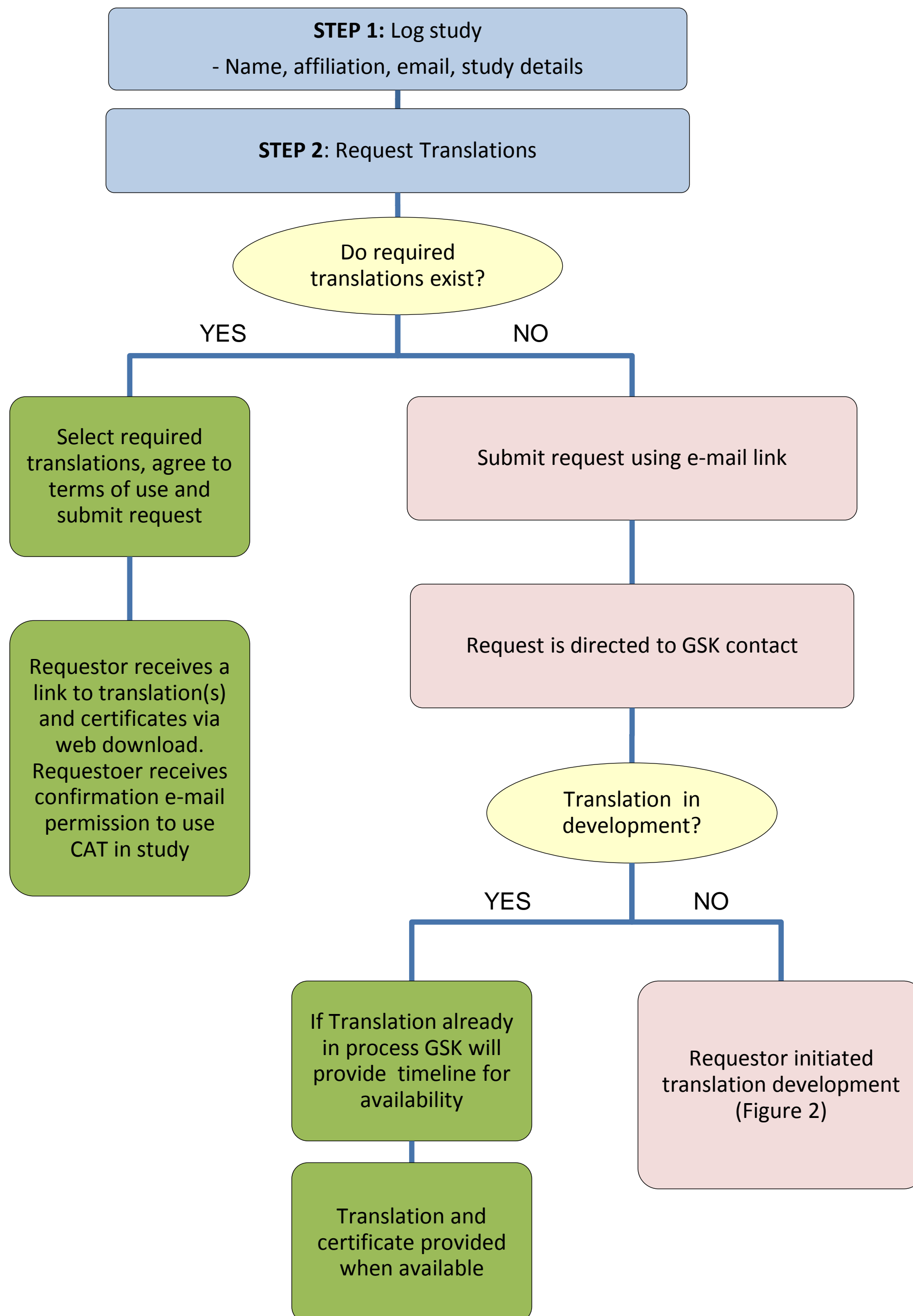

Figure 1: Request to use CAT

How can I get a new translation made?

The CAT is used as a Clinical Outcomes Assessment (COA). It is therefore important that new translations are linguistically validated to the highest standards. Internationally recognised processes for translation (Wild et al) are required for all new translations which are commissioned. The translation process is summarised in figure 2. All new translations must be approved by the CAT Governance Board before they will be posted to the website.

GSK will maintain the database of translations and make these available to all researchers. New translations and supporting documents must be submitted to GSK using the (add CAT e-mail when active) so they can be made available for other researchers to help us all understand the impact of COPD.

Why do I have to use approved translations?

To maintain the global use of the CAT in research it is extremely important that only one translation is used for each language in a country. It is for this reason that GSK maintains the copyright of the CAT, provides advice on translations in progress and manages the translation database.

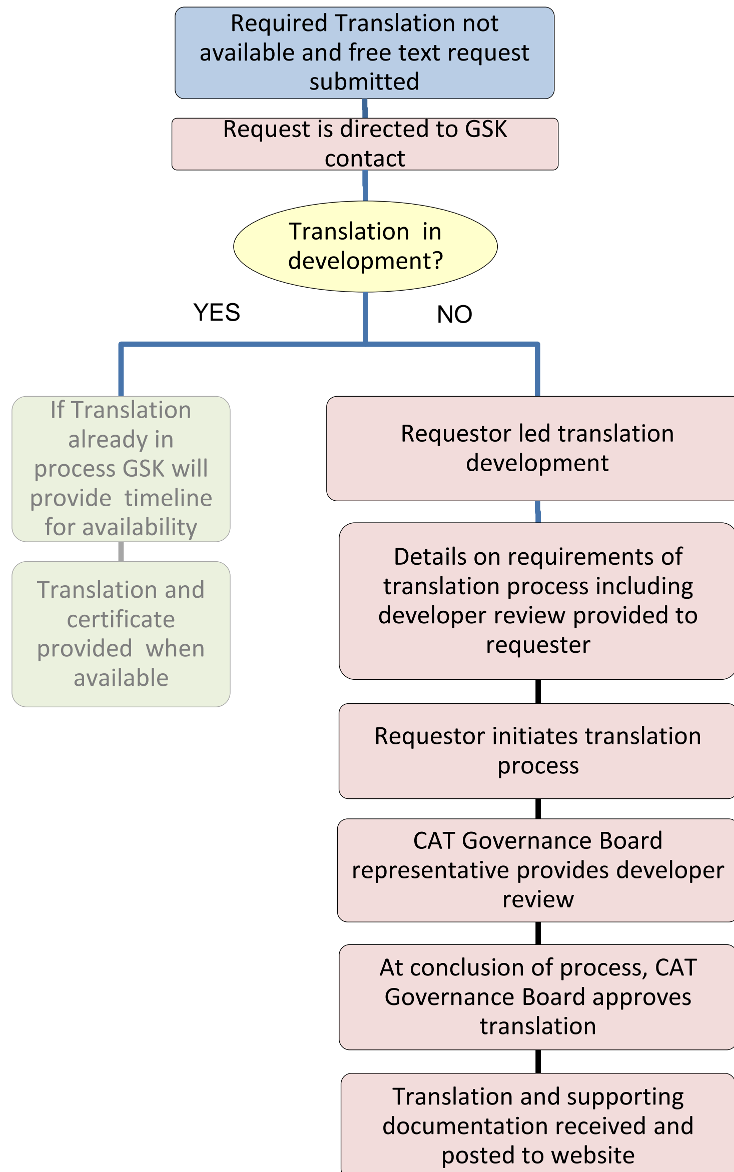

Figure 2: Process for Development of New Translations

Can the 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 e-COA). A full list of the devices on which CAT has been tested and approved for use is available on the CAT website (link)

Migration of the CAT to a new eCOA device should be conducted and evaluated using international guidelines (Coons et al). Further details are provided in the next section of this user guide.

Why do you need to collect my details?

We collect the minimum data required to accurately provide permission to use the CAT in research and to provide translations. In addition we will be able to notify you if any issues arise with new translations.

The CAT Governance Board intends to work with the COPD Foundation Consortium for the Qualification of Biomarkers in COPD to obtain recognition of the CAT as a Drug Development tool with the US and EU regulators (FDA and EMA). The pooling of anonymized data from well controlled research studies could be key to this process.

What study details will you collect?

We will collect the minimum amount of information to assess that the use of CAT is appropriate. For most commercial studies this will be the Clintrials.gov number and study title. For academic studies an IRB or ethics committee reference or university reference number and study title will be needed. Where insufficient information is available publically to ascertain appropriate use of the CAT you may be asked to provide further detail in the form of a brief study synopsis on behalf of the Governance Board

Use of the CAT on electronic data collection platforms

As indicated above, the CAT has been tested and used on a number of electronic data collection devices (e-COA). A full list of the devices on which CAT has been tested and approved for use is available on the CAT website (link)

Can you tell me more about eCOA's?
There are two main categories of eCOA administration platforms: voice/auditory devices (primarily telephone-based and commonly referred to as interactive voice response (IVR) and screen text devices (such as desktops, laptops and tablets) which provide the respondent with a computerized version of the PRO items and responses in a visual text format. CAT has been migrated to a number of screen text devices.

Does migrating a PRO to an eCOA make a difference?
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.

What if I want to develop and use a new e-PRO adapted from the CAT?

Migration of the CAT to a new e-COA device needs to be supported by evidence to demonstrate the comparability, or measurement equivalence, of the ePRO to the paper-based CAT. Important considerations with regard to 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[15].

Are there specific requirements for migrating CAT to a new eCOA platform?

When migrating 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 CAT into a ‘bring your own device’ data collection method should take into account the screen sizes likely to be used in any study[16].

The CAT governance board will accredit new presentations of the CAT on eCOA which will then be listed on the website at the subsequent update. Further information on the requirements for migration can be obtained here (link to contact us e-mail)

Other materials for Researchers

Other materials are available on the website to assist your research

Within the website we have provided links to the publications describing the development of the CAT. You may wish to refer to these key references in your protocol, analysis plan and subsequent publication.

The website also includes a bibliography which covers global experience with the CAT in different countries and clinical situations, demonstrating the responsiveness of the CAT when used to evaluate pharmacologic interventions, onset and recovery from exacerbations, and use to monitor the effects of pulmonary rehabilitation. The bibliography will be updated twice every year following the ATS and ERS congresses. Production of the bibliography uses standard literature search terms on four databases (Embase, PubMed, Scopus, Searchlight).

While this user guide includes guidance on the migration of CAT to electronic data collection devices the website includes a list of eCOA which have been endorsed by the CAT Governance Board.

CAT Development Steering Group

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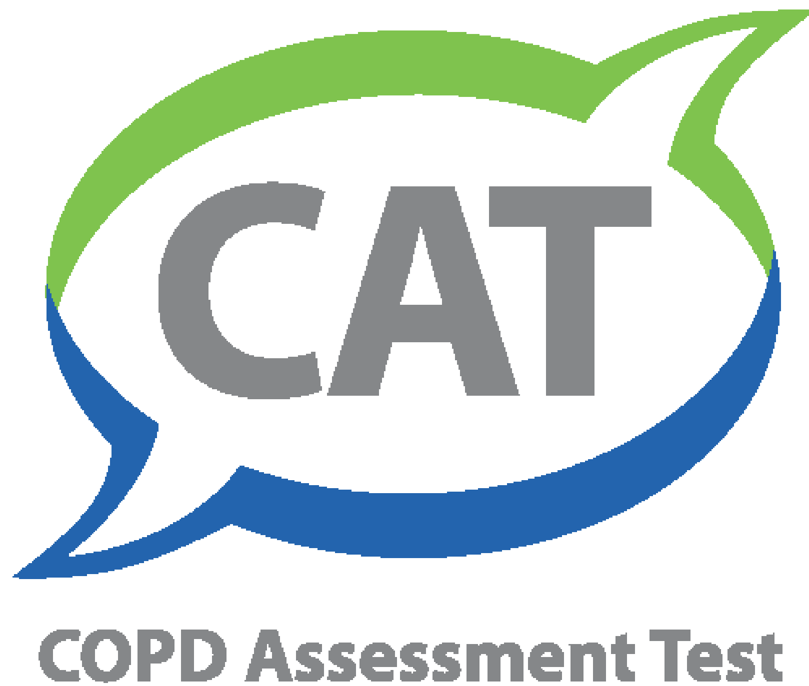

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