NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Diagnostics Advisory Committee (DAC) meeting minutes

**Minutes:** Confirmed

**Date and time:** 17 November 2021

**Location:** Via Zoom

## Attendees

Committee members present

1. Mark Kroese (Chair) Present for all items
2. Liz Adair Present for all items
3. Rebecca Allcock Present for all items
4. John Cairns Present for all items
5. Sam Creavin Present for all items
6. Jim Gray Present for all items
7. Neil Hawkins Present for all items
8. Patrick McGinley Present for items 1 – 1.4.3
9. Brendan Meyer Present for all items
10. Karen Sennett Present for all items
11. Alasdair Taylor Present for all items
12. Brian Shine Present for all items
13. Matt Stevenson Present for all items

NICE staff present

Sarah Byron, Programme Director Present for all items

Rebecca Albrow, Associate Director Present for all items

Frances Nixon, Health Technology Assessment Adviser Present for all items

Vera Unwin, Health Technology Assessment Analyst Present for items 2 – 2.5.3

Sophie Harrison, Associate Health Technology Present for items 1 – 1.4.3

Assessment Analyst

Donna Barnes, Project Manager Present for all items

Alex Sexton, Administrator Present for all items

External assessment group representatives present

Mariana Bacelar, Principal Health Economist, Present for items 1 – 1.3.7

BMJ-TAG

Sam Baron, Principal Clinical Evidence Analyst, Present for items 1 – 1.3.7

BMJ-TAG

Steve Edwards, Director of Health Technology Present for items 1 – 1.3.7

Assessment, BMJ-TAG

Ana Duarte, Research Fellow, Present for items 2.1 – 2.4.7  
Centre for Health Economics, University of York

Mark Simmonds, Senior Research Fellow, Present for items 2.1– 2.4.7

Centre for Reviews and Dissemination, University of York

Marta Soares, Senior Research Fellow, Present for items 2.1 – 2.4.7  
Centre for Health Economics, University of York

Specialist Committee Members present

Zehra Arkir, Consultant clinical scientist (biochemist) Present for items 1 – 1.4.3

biochemical sciences, Viapath

Jenny Epstein, Consultant Paediatric Gastroenterologist, Present for items 1 – 1.4.3  
Chelsea and Westminster Hospital

Rebecca Harmston, Lay specialist committee member Present for items 1 – 1.4.3

Jack Satsangi, Professor of Gastroenterology, Present for items 1 – 1.3.3  
University of Oxford

Matthew Callister, Consultant Respiratory Physician, Present for items 2 – 2.5.3

Leeds Teaching Hospital

Philip Crosbie, Senior Lecturer in Respiratory Medicine, Present for items 2 – 2.5.3

University of Manchester

Jesme Fox, Lay specialist committee member Present for items 2 – 2.5.3

Seamus Grundy, Consultant Respiratory Physician, Present for items 2 – 2.5.3

Salford Royal Hospital

Emma O’Dowd, Consultant Respiratory Physician, Present for items 2 – 2.5.3

Nottingham University Hospitals NHS Trust

Janette Rawlinson, Lay specialist committee member Present for items 2 – 2.5.3

James Wilson, Consultant Clinical Oncologist, UCLH Present for items 2 – 2.5.3

Observers present

Cristina Fernandez-Garcia, Health Economist and Present for items 1 – 1.3.7 Bioethicist, Newcastle University and 2 - 2.4.7

Giovany Orozco, Research Assistant, Present for items 2 - 2.4.7  
Newcastle University

Emilene Coventry, Senior Medical Editor, NICE Present for items 1 – 1.4.3

Lucinda Evans, Coordinator, NICE Present for items 1 –1.3.7

and 2 - 2.4.7

Benjamin Gregory, Business Analyst, NICE Present for items 1 – 1.4.3

Laura Marsden, Public Involvement Adviser, NICE Present for items 2 – 2.5.3

Ian Mather, Business Analyst, NICE Present for items 2 – 2.5.3

Benjamin Pearce, Senior Medical Editor, NICE Present for items 2 – 2.5.3

## Minutes

### Evaluation of PredictSURE IBD and IBDX to guide treatment of Crohn's disease

* 1. The Chair welcomed members of the committee and other attendees present to the meeting.
  2. The Chair noted apologies from standing committee members Keith Abrams, Diane Davies, Michael Messenger, Alexandria Moseley, and Shelley Rahman Haley and from specialist committee members Shaji Sebastian and Tracey Tyrrell.
  3. Part 1 – Open session
     1. The Chair welcomed external assessment group representatives, members of the public and company representatives from Glycominds LLC and PredictImmune Ltd.
     2. The Chair asked all committee members to declare any relevant interests in relation to the item being considered. The following standing committee members had notified these interests in advance of the meeting:
* John Cairns declared financial interests as he had advised Astellas on health economic modelling for roxadustat (interest ceased May 2021) and Takeda on the economic evaluation of maribavir (interest ceased August 2021). It was agreed that these interests would not prevent John Cairns from participating in the meeting.
* Neil Hawkins had declared a financial interest as a company (Visible Analytics Ltd) in which he has a financial interest (directorship) is currently conducting a systematic review for a manufacturer of pharmacological treatments for Crohn’s disease. The review does not concern diagnostics testing and is not commissioned by, and does not consider any products marketed by, PredictImmune Ltd or Glycominds, LLC. It was agreed that this interest would not prevent Neil Hawkins from participating in the meeting.
* Patrick McGinley declared a financial interest as he is a Faculty Member of MTech Access, advising on NHS finance flows, and receives an honorarium for this. He also declared non-financial personal and professional interests as he is a Strategic Council member of the All-Party Parliamentary Group (APPG) on Obesity, He is also the Hon Treasurer for the Association for Study of Obesity (ASO). It was agreed that these interests would not prevent Patrick McGinley from participating in the meeting.
* Alistair Reid declared a non-financial professional and personal interest as he is an elected member of the governing council of the Royal College of Radiologists and a member of the British Society for Gastrointestinal and Abdominal Radiology (BSGAR). It was agreed that these interests would not prevent Alistair Reid from participating in the meeting.
* Karen Sennett declared a financial interest as she is a GP partner at an NHS GP practice. It was agreed that this interest would not prevent Karen Sennett from participating in the meeting.

The following specialist committee members had notified these interests in advance of the meeting:

* Zehra Arkir declared non-financial personal and professional interests as she is the consultant lead for Viapath Analytics anti-TNF therapeutic drug monitoring laboratory service and laboratory lead/co-investigator for the following studies: Study of the Golimumab Exposure-Response Relationship using Serum Trough Levels (GO-LEVEL); and Investigation of the Faecal loss of Vedolizumab and its role in influencing serum drug levels, Outcomes and Response in ulcerative colitis (FAVOUR). It was agreed that these interests would not prevent Zehra Arkir from participating in the meeting.
* Jenny Epstein declared financial interests as she had received sponsorship from Abbvie to attend ECCO (European Crohn’s and Colitis) meeting in 2018, and she undertakes private practice but does not see patients with Crohn’s disease in her private practice. She also declared non-financial professional and personal interests as she is Medical Advisor to CICRA (Crohn’s in Childhood Research Association) and a Member of BSPGHAN (British Society of Paediatric Gastroenterology Hepatology and Nutrition) IBD working group. It was agreed that these interests would not prevent Jenny Epstein from participating in the meeting.
* Rebecca Harmston declared the following indirect interests: lay representative on JRCPTB Paediatric Cardiology Specialist Advisory Committee; member of Parent Carer Advisory Group, Royal College of General Practitioners; lay member of NICE Technology Appraisal Committee (ceased August 2021); epidemiology patient partner for UK Arthritis (ceased 2020); lay member of Pharmacy Research UK; lay member of the NIHR and Imperial College Invitro Diagnostics panel; public representative on the NHS Public and Patient Voices Panel with the Genomics Clinical Reference Group; lay member on the ANTRUK Education Committee; HQIP Understanding Health Data Access Expert Advisory Group member; Patient Advisory Group member for AlphaBiomics who have developed a diagnostic test RxSelexTM to predict whether or not patients with moderate to severe inflammatory bowel disease (IBD) are likely to respond positively to biologic drugs; patient co-applicant on the EXTEND trial which is looking at antibiotic treatment of complicated intra-abdominal infections; patient expert on NICE Scientific Advice Project - Knee pain associated with Osteoarthritis SA710; patient member with the NHS SBRI health care panel; lay member with the NIHR Open Research Board; Qresearch data hub - lay/patient committee member; pioneer data hub - lay/patient committee member; HDRUK - lay/patient committee member; member of the Gut Reaction Patient Advisory Committee Crohn’s and Colitis UK; spouse is a Senior Director of Regulatory Affairs at PPD in Cambridge (his work is covered by confidentiality agreements). It was agreed that these interests would not prevent Rebecca Harmston from participating in the meeting.
* Jack Satsangi declared an indirect interest as he has a research interest in biomarker discovery. He also declared non-financial professional and personal interests as he is a Board Member representing Royal College of Physicians, UK IBD Registry. He is research active in identifying biomarkers for test development for the disease area of this evaluation and similar target population. He is co-author and provider of data for the paper “Transcription and DNA Methylation patterns of blood derived CD8+ T cells are associated with age and Inflammatory Bowel Disease but do not predict prognosis” <https://doi.org/10.1053/j.gastro.2020.08.017>. It was agreed that these interests meant that Jack Satsangi should be partially excluded from discussions and he attended for the first part of the part 1 discussions only.
  + 1. The Committee proceeded to discuss the additional analysis provided by the External Assessment for PredictSURE IBD and IBDX to guide treatment of Crohn's disease.
    2. The Committee was asked if there were any specific equality issues to consider in relation to this assessment.
    3. The Chair asked the representatives of the manufacturers whether they wished to comment on any matters of factual accuracy.
    4. The Chair thanked the manufacturer representatives, the EAG and public observers for their attendance at the meeting.
    5. The Chair explained that “representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)” and all public attendees left the meeting.
  1. Part 2 - Closed session
     1. The committee discussed confidential information submitted for this item.
     2. The committee then agreed on the content of the Diagnostics Guidance Document (DGD). The committee decision was reached by consensus.
     3. The committee asked the NICE technical team to prepare the DGD in line with their decisions.

### Evaluation of EarlyCDT Lung for lung cancer risk classification of solid pulmonary nodules

* 1. The Chair welcomed members of the committee and other attendees present to the meeting.
  2. The Chair noted apologies from standing committee members Keith Abrams, Diane Davies, Patrick McGinley, Michael Messenger, Alexandria Moseley, and Shelley Rahman Haley and from specialist committee members Helen Johnstone and Eric Lim.
  3. The committee approved the minutes of the committee meeting held on 16 September 2021.
  4. Part 1 – Open session
     1. The Chair welcomed external assessment group representatives, members of the public and company representatives from Oncimmune Ltd.
     2. The Chair asked all committee members to declare any relevant interests in relation to the item being considered. The following standing committee members had notified these interests in advance of the meeting:
* John Cairns declared financial interests as he had advised Astellas on health economic modelling for roxadustat (interest ceased May 2021) and Takeda on the economic evaluation of maribavir (interest ceased August 2021). It was agreed that these interests would not prevent John Cairns from participating in the meeting.
* Neil Hawkins declared a non-financial professional and personal interest since, as part of university employment, he may have potential involvement in a TSET (Technology Specific Evaluation Team). It was agreed that this interest would not prevent Neil Hawkins from participating in the meeting.
* Alasdair Taylor declared non-financial professional and personal interests as he is a core member of his employing Trust's lung cancer MDT since 2016; he has no direct involvement in research relevant to the topic and has not published on the topic. He also declared an indirect interest as he is an elected member of the council of the Royal College of Radiologists, representing the faculty of clinical radiology. It was agreed that these interests would not prevent Alasdair Taylor from participating in the meeting.

The following specialist committee members who were present at the meeting had notified these interests in advance of the meeting:

* Matthew Callister declared non-financial professional and personal interests:
  + He co-chaired the 2015 British Thoracic Society Pulmonary Nodule Guidelines. The role of biomarkers in discriminating benign from malignant nodules was considered and published evidence regarding EarlyCDT-Lung was reviewed. The GDG commented that "there are no reports evaluating the performance of this test in a cohort of patients with pulmonary nodules" and therefore concluded that its efficacy in discriminating malignant from benign nodules was unknown. The summary evidence statement was "Biomarkers do not offer sufficient accuracy to differentiate malignant from benign nodules" and the recommendation was "Do not use biomarkers in the assessment of pulmonary nodules" Grade D.
  + He is Chief Investigator for the Yorkshire Lung Screening Trial (YLST), and a co-applicant on the YLST Biomarker Study (a nested sub-study within YLST - PI Dr Philip Crosbie, University of Manchester). As of December 2020 the study collaborated with Everest Diagnostics, a company developing circulating biomarkers of lung cancer. He has no personal connection with the company in question, has received no personal payments and owns no shareholdings of other investments in this company.
  + The YLST biomarker company is now planning on being one site for IDx lung. The latter study is run by the University of Southampton, is funded by Innovate UK, and is testing a number of biomarkers in lung screening and nodule evaluation - one of which is Early CDT lung. He is not a listed co-investigator for IDx itself but will be a co-author on any paper published looking at the efficacy of these tests. He receives no personal payments for any of these collaborations.
  + The EarlyCDT-Lung test has been proposed as a tool for identifying people at higher risk of lung cancer who might benefit from low-dose CT screening for lung cancer. This is a distinct indication for the test than the one under review here (discrimination of malignant from benign pulmonary nodules once detected). The former indication was the subject of the Early Detection of Lung Cancer in Scotland (ECLS), first presented in abstract form at the World Conference on Lung Cancer 2019 and shortly to be published in the European Respiratory Journal. He was asked to write a blog for the British Thoracic Oncology Group regarding lung cancer screening research presented at WCLC2019 (https://www.btog.org/blog/lung-cancer-screening-at-wclc-2019/), and has recently co-authored an editorial for publication in the European Respiratory Journal alongside the main trial paper. Both the blog and subsequent editorial raise some concerns about the design of ECLS and the way in which the performance of the test has been reported by the trial group. The recommendation in both is for further research to be undertaken to determine the role of EarlyCDT in this scenario. Use of EarlyCDT in this way is not the matter under consideration in this review.

It was agreed that these interests would not prevent Matthew Callister from participating in the meeting.

Philip Crosbie declared the following financial interests: Everest Detection, a biotechnology startup company - consultancy fees and share options for lung cancer early detection and screening. The company collaborate with the Yorkshire Lung Screening Trial biomarker study which he leads. Everest Detection do not currently have a product. He received an honoraria from Novartis for lung cancer survey design (interest ceased 2020), and from AstraZeneca for a lung cancer screening talk and round table discussion (interest ceased 2020). He also declared non-financial personal and professional interests as he contributed to NICE Medtech Innovation Briefing related to EarlyCDT-Lung; and he is chief investigator Yorkshire Lung Screening Trial Biomarker study (assess EarlyCDT-Lung in lung screening cohort). It was agreed that these interests would not prevent Philip Crosbie from participating in the meeting.

* Jesme Fox declared financial interests as her employer, Roy Castle Lung Cancer Foundation (RCLCF), has received grants/donations from multiple pharmaceutical and commercial businesses. These have been for specified projects (eg, conference organisation, patient information leaflets, Global Lung Cancer Coalition etc.) and not core funding. She has presented at many conferences and participated in advisory boards, organised by multiple pharmaceutical companies. Over the past year, she has participated in virtual Advisory Boards for Boehringer Ingelheim, BMS, AstraZeneca, Novartis, Debiopharma and Takeda (see dates below). In lieu of her time, donations have been given by the company to RCLCF. At no time has she personally accepted an honorarium. The dates were: Boehringer Ingelheim Advisory 26/02/21, BMS Advisory 09/12/20, 02/02/21, 12/03/21, 17/07/21, 22/07/21, AstraZeneca Advisory 12/03/21, Takeda Advisory 28/06/21, Novartis Advisory 10/12/20, Debiopharma 22/06/21, 07/09/21.

She also declared non-financial professional and personal interests as follows: she is the Medical Director, Roy Castle Lung Cancer Foundation; Branch President, Northwest Somerset Branch of Parkinsons' UK; Secretary, Global Lung Cancer Coalition; Member- British Thoracic Oncology Group; Member - International Association for the Study of Lung Cancer; Member -Lung Cancer and Mesothelioma Clinical Expert Group; Member - NHSE&I Early Detection 'Task and Finish Group'; Member - NHSE&I Lung Cancer Screening Advisory Group.

She also declared the following indirect interests: Roy Castle Lung Cancer Foundation is a registered charity, with an interest in ensuring equitable access to best practice diagnostics, treatment and care for all lung cancer patients. She represents the Global Lung Cancer Coalition on the Board of the Lung Ambition Alliance (the LAA currently receives funding from Astra Zeneca and Guardant Health). She represents the Global Lung Cancer Coalition on the Global Cancer Coalition Network.

It was agreed that these interests would not prevent Jesme Fox from participating in the meeting.

* Seamus Grundy declared a financial interest as he is a Clinical Expert Reviewer for British Standards Institute. He provides expert opinion to the British Standards Institute for Respiratory Devices. He has not provided any opinion directly or indirectly related to the technology under review by this committee. He also declared non-financial professional and personal interests as he is the Chief Investigator for the Salford Lung Health Check Biomarker Study and is collaborating with Everest Detection Ltd. The research relates to developing biomarkers to improve the early detection of lung cancer within lung cancer screening programs using blood and other biological samples such as urine or saliva. He further declared a grant application in collaboration with QURE for NHS Innovation awards to evaluate the impact of regional roll out of AI reporting of chest x-rays on diagnostic capacity and efficiency.

It was agreed that these interests would not prevent Seamus Grundy from participating in the meeting.

* Emma O'Dowd declared a non-financial professional and personal interest as she is co-author on research looking at the role of artificial intelligence in pulmonary nodule risk stratification and co-author on editorials relating to nodules in lung cancer screening. However, these are not specifically related to the matter under review, there is no ongoing research related to this, and she does not have any affiliations related to this research. It was agreed that this interest would not prevent Emma O’Dowd from participating in the meeting.
* Janette Rawlinson declared financial interests as she was a Lay member of Sandwell & West Birmingham Clinical Commissioning Group (paid for governance role via payroll/ contract for services not employment –– 5-7 days per month) and a member of the SWB Cancer steering group and contributed to producing a video for HCPs to raise awareness of CXR/earlier detection of LC (interest ceased March 2021). She also declared a financial interest due to her involvement with a study by Optellum to determine the impact of AI for lung cancer nodule risk stratification on service intervention. She is working with PPI lead on the optimum way to engage participants for a workshop to assess people’s acceptability/understanding of machine learning for reading pulmonary images and has received an honorarium for the first piece of work in line with INVOLVE rates.

She also declared non-financial professional and personal interests as she is a patient representative on the NHSE Lung screening advisory group, contributing on behalf of patients/carers/public to issues affecting people affected by screening and discuss progress, challenges and potential solutions. She is a patient representative on the NHSE lung cancer Clinical Expert Group; this produced guidance on managing pulmonary nodules including patient information in April 2017 and contributed to patient information for national lung screening pilot projects and contributed to amendments in policy/process re lung cancer (especially during pandemic) from a patient /public perspective. She is a member of the patient literature panel for Roy Castle Lung Cancer Foundation, regularly contributes to patient information updates relating to lung cancer, treatment and living with lung cancer, attended several related events. She is a co-author on a [BMJ article](https://www.bmj.com/content/371/bmj.m3673.full?ijkey=C6mMQjTaAM3DD4S&keytype=ref)on pulmonary nodules. She is on the NCRI advanced disease lung group, contributing to reviews of lung cancer trials portfolio, early design studies, annual trials day and annual report and Never Smokers lung cancer workstream. She is a steering committee member for British Thoracic Oncology Group (BTOG) representing patient/carers in charity responsible for education on all thoracic malignancies. She is on the ERS/ELF patient advisory group on lung cancer and lung screening and attended several consultative events. She is a NCRAS Clinical reference group member of RICCR working group (review of informed consent cancer registry). She is the patient representative on the West Midlands Cancer Alliance – lung cancer & mesothelioma expert advisory group, contributing patient/carer perspective on lung cancer issues. She is the patient representative for Cancer Research UK Stratified Medicine Programme, adding patient/carer perspective for, consideration of additional arms/treatments/changed gene panels, concerns, etc and as trial approaches its end review potential publication and dissemination routes. Also for Cancer Research UK she is the patient representative panel member for CERP, assessing funding bids, review trials’ progress, review CTU impact of Covid 19. She is a member of the EORTC Patient Panel. She is the Patient Public voice partner to the clinical reference group for NHSE Specialist commissioning services specialist cancer surgery. She is a co-author on a [Thorax paper](https://thorax.bmj.com/content/early/2021/10/28/thoraxjnl-2021-217142)on selecting eligible participants for lung cancer screening. It was agreed that these interests did not prevent Janette Rawlinson from participating in the meeting.

* James Wilson declared a financial interest due to private practice. It was agreed that this interest would not prevent James Wilson from participating in the meeting.
  + 1. The Committee proceeded to discuss the comments made during the public consultation for the EarlyCDT Lung for lung cancer risk classification of solid pulmonary nodules topic.
    2. The Committee was asked if there were any specific equality issues to consider in relation to this assessment.
    3. The Chair asked the representatives of the manufacturers whether they wished to comment on any matters of factual accuracy.
    4. The Chair thanked the manufacturer representatives, the EAG and public observers for their attendance at the meeting.
    5. The Chair explained that “representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)” and all public attendees left the meeting.
  1. Part 2 - Closed session
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### Date of the next meeting

The next meeting of the Diagnostics Advisory Committee (next topic) will be held on 19 January 2022.