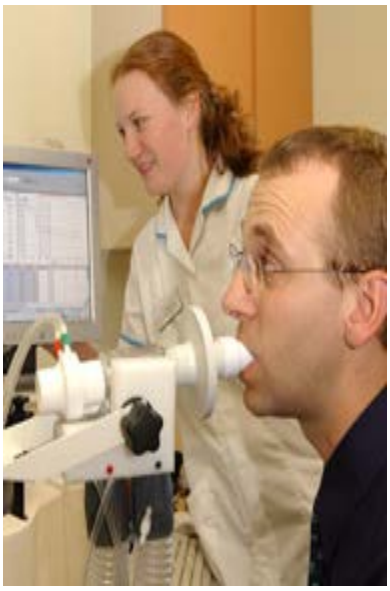
National Institute for Health Research

Bradford Teaching Hospitals NHS
NHS Foundation Trust



L to R: Dr Saralaya, Nabeela Nazir Ahmed, K Regan,

Laura Walker, Stephen Cox

British Lung Foundation

Contents:

Who We Are

The respiratory research unit at Bradford Teaching Hospitals NHS Foundation Trust was first established in 2009, by Dr Dinesh Saralaya and Karen Regan, Senior Research nurse. The unit commenced recruitment in September 2009. In our very first multi-centric COPD trial we became the highest recruiter in the UK. Since then we have carried out 27 multi-centric Phase III chronic obstructive pulmonary disease (COPD) and Phase II severe asthma trials. We have continuously experienced unparalleled success with trials focusing on COPD and have become one of the centres of choice for commercial pharmaceutical companies who wish to carry out commercial trials in COPD and severe asthma in the UK. We always aim to provide good quality clinical data while never compromising patient safety. We were inspected by the Medicinal and Health Products Regulatory Agency (MHRA) in January 2012. We have also had 3 company audits of our practise and have been complimented as an exemplary site.

We are part of Bradford Teaching Hospitals NHS Foundation Trust (BTHFT)

Mission Statement

We are an extremely motivated team providing **high quality care** with an aim to promote **respiratory health through trials of new treatments**. We endeavour to provide clinical data of the highest quality by consistently meeting our recruitment targets and ensuring all documentation is **accurate** and **reliable**.

Support & Services for Industries and Commercial Research

Through fantastic facilities at Bradford Royal Infirmary and highly specialised research staff who focus on respiratory, we hope to continue expanding our knowledge and improve our

patient care and research capacity. We are always interested in working with pharmaceutical and biotechnology companies.

It is the mission of the NIHR to facilitate and aid commercial and industrial researchers with their CTIMP, observational and medical device research. The NIHR can aid any step of research process and help you get in touch with us. For more information, contact the Yorkshire & Humber CRN Industry manager- industry.crnyorkshumber@nihr.ac.uk

How We Promote and Implement High Quality Research

Expert Researchers and Notable Publications:

Dr Dinesh Saralaya, who set up the research team in 2009, has already been involved in 27 Phase III and even 3 Phase II trials and has extensive experience in respiratory medicine. In many of these trials he has been the Chief Investigator in the UK. In 2014 he has been awarded a certificate of recognition by NIHR for exemplary support to the NIHR CLRN with regards to the respiratory commercial research portfolio.

Dr Saralaya and his team are also assisted by Dr BK Jacob and Dr Aziz who help as sub-investigators.

You can see some of Dr Saralaya's recent relevant publications, many of which relate to in-depth study into Omalizumab, a humanized monoclonal antibody based on IgE (Immunoglobulin E), which is hoped to act as a long term solution for suffers of asthma:

Notable publications from our Research Unit

Real-life effectiveness of omalizumab in patients with severe persistent allergic (IgE-mediated) asthma at a single UK hospital
Simons A, Regan K, Aziz A, Saralaya D, *AJRCCM*, May 2010

Real-life effectiveness of omalizumab in patients with severe persistent allergic (IgE-mediated) asthma: Pooled data from three UK centres
Britton M, Howes T, Boland A, Saralaya D, Hepburn D, Nordstrom M, Welham K, Regan K, Kasujee, *ERJ*, September 2011

Real-life effectiveness of omalizumab in patients with severe persistent allergic (IgE-mediated) asthma: Pooled data from three UK centres
Britton M, Howes T, Boland A, Saralaya D, Hepburn D, Nordstrom M, Regan K, Kasujee, *ERJ*, September 2012

Long-term effectiveness of omalizumab in patients with severe persistent allergic (IgE-mediated) asthma: real-life data from three UK Centres
Britton M, Howes T, Boland A, Saralaya D, Hepburn D, Nordstrom M, Regan K, Kasujee, *ERJ*, September 2012

Improved Metered Dose Inhaler Technique when a co-ordination cap is used
Wahisa Azouz, Jessica Campbell, D Saralaya. H Hosker, H Crystyan. *J of Aerosol Medicine* May 2013

Enhanced training on how to use a dry powder inhaler (DPI) improves the inhalation manoeuvre (IM) of patients with asthma (child 6–17yrs and adult >17yrs) or COPD and in healthy adults (HA) when they use a Spiromax® (S) and Turbuhaler® (T) DPI, Azouz W, Chetcuti P, Hosker H, Saralaya D, Chrystyn H , ERJ September 2013

Inhalation characteristics with Spiromax® (S) versus Turbuhaler® (T) dry powder inhalers (DPIs) in healthy adults (HA) and in patients with asthma (A) or COPD Azouz W, Chetcuti P, Hosker H, Saralaya D, Chrystyn H ,ERJ September 2013.

Lung function response to omalizumab in severe allergic asthma in UK clinical practice – APEX II study . Dinesh Saralaya[1], Andrew Menzies-Gow[2], Ian Clifton[3], Adel Mansur[4], Alan Hart-Thomas[5], Robert Niven[6], APEX Study Investigators , ERS 2014.

First Class Facilities:

Our site has been audited on numerous occasions. We have had a MHRA inspection in January 2012 from which we received a glowing report and were told our documentation was “exemplary”. We have also had internal audits by the pharmaceutical companies in which we have always had minimal audit findings.

Patient Public Involvement (PPI):

We see patient and public involvement as a very important aspect of our research, and regularly hold events where patients and relatives are invited to voice their opinions or queries. We also take this as an opportunity to disseminate information and use these occasions to improve our service.

We hold our events at locations away from the hospital to enable people to speak openly. As well as holding these events, we have taken part in the research department open days.

Extensive Patient Database

We collect information via a database of patients that have any of the conditions we look for with the trials. These come from looking through consultant letters and from Dr Saralaya’s clinic where he hand picks patients he thinks may be suitable for the trials. The database has over 600 patients on it. As of yet we have not had to rely on any advertising or outside help to recruit.

Improved Research Capacity

We have the experience and facilities not only to undertake Phase III trials but also more complicated Phase II studies.

Previous Research

Since our set up in 2009, we have successfully carried out 27 multi-centric COPD and asthma trials.

In the very first trial that respiratory research took part in as a team we managed to be the highest recruiters in the UK. Our target was to recruit 5 patients and we managed to recruit 11. It was a 12 week treatment, multicentre, randomised, parallel group, blinded, double dummy study, to compare the efficacy and safety of Indacaterol delivered via a SDDPPI with Tiotropium delivered via a handihaler, in patients with moderate to severe COPD.

After successfully completing the first trial we then went on to take part in many other COPD trials for Novartis (a Swiss-based pharmaceutical company). These included six successful trials, specialising in COPD.

We have a very strong partnership with various pharmaceutical companies and have been a centre of their preference to carry out both COPD and asthma trials. We have carried out trials for

1. Novartis
2. GlaxoSmithKline
3. Astra Zeneca
4. Almirall
5. Bayer
6. KaloBios
7. Chiesi
8. Boehringer Ingelhiem
9. Pfizer

Following these we took on our first asthma trial in 2012 this was the CQAW03A2206- A randomised, placebo-controlled, dose-ranging, multi-centre trial of QAW039 to investigate the effect on FEV1 and ACQ in patients with moderate to severe, persistent, allergic asthma, inadequately controlled with ICS therapy. We managed to recruit 3 patients to this trial which involved 10 visits to clinic over a period of 52 weeks.

Public News Articles We're Featured in

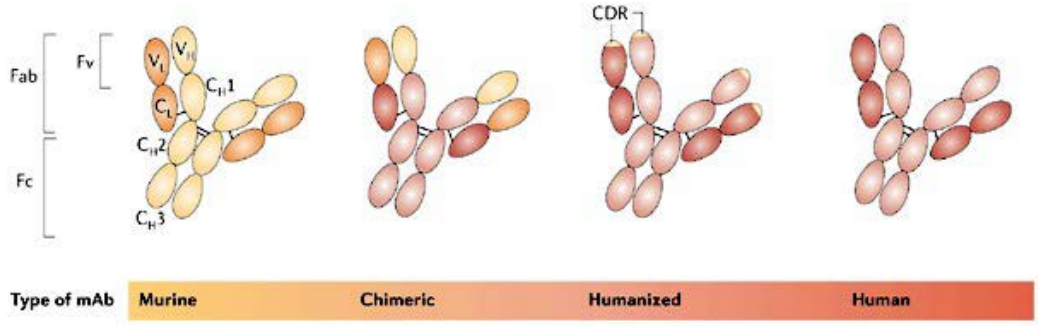
You can read more about one of recent fantastic success stories, which was published in the Yorkshire Evening Post (Yorkshire Tabloid), here -

- ***"This is the third successive "world-first" milestone that the consultant and the Bradford respiratory research team have achieved and comes as a result of their success in attracting more commercial research into the city and region"***

And here, in the Telegraph & Argus (Bradford Tabloid):
For Lung Disease

For Severe Asthma

Find out about immunoglobulin & antibody based medicines, e.g.omalizumab, and the focus of work from KaloBios work;



(Image from - Nature Reviews Cancer **6**, 714-727 (September 2006))
This class of drug is at the forefront of respiratory disease research.

Current Research

We are currently conducting 6 trials for a range of respiratory complaints including COPD (chronic obstructive pulmonary disease), asthma and bronchiectasis, with many more planned for the future.

Trials that are currently on-going are:

- A placebo and active controlled study to assess the long term safety of once daily CQVA149 for 52 weeks in COPD patients with moderate to severe airflow limitation. This is to be carried out in approximately 20 countries around the world involving 1224 patients in which 50 of these will be in the UK. As a team we originally had a target of 10 patients but we have currently recruited 25 and recently agreed to recruit 3 more.

- An active controlled study to compare CQVA149 with Salmeterol/fluticasone for 52 weeks in patients with moderate to very severe COPD. We started recruiting on the 29/07/2013 and have already screened 10 patients. We achieved global first patient with this trial which is a massive achievement for us and research in the UK.

- A study designed to obtain information on the safety and the effectiveness of an experimental drug called KB003 when it is given to patients with asthma which are inadequately controlled by corticosteroids. The main purpose of the study is to determine if KB003 will help lung function and reduce asthma symptoms. The study lasts 36 weeks and medication is given every 4 weeks. We screened 10 patients and recruited 3, 2 of which are still receiving medication.

- A phase III study is to evaluate the efficacy of a new mepolizumab prescription every 4 weeks versus placebo on the frequency of clinically significant exacerbations in adult and adolescent subjects with severe, uncontrolled, refractory asthma. The study will run for a

period of 28 weeks and there is an opportunity to participate in the open label extension providing the criteria is met. We currently have 3 patients receiving treatment on this trial. The purpose of this study is to assess the effects (good or bad) of mepolizumab when given for one additional year (this is the extension of the trial mentioned above MEA115588). The study medication, mepolizumab, is not yet approved for doctors to treat patients with severe asthma. A maximum of approximately 660 people in 19 countries will take part in this study. In the UK approximately 15 -20 subjects will take part. We aim to recruit 3 of the 15-20 patients recruited from the UK.

- The purpose of this study is to find out if the oral investigational drug BAY 85-8501 is safe and effective in the treatment of non-cystic fibrosis bronchiectasis (non-CF BE). BAY 85-8501 is an experimental drug which has not yet been approved by Health Authorities in any country for the treatment of non-CF BE. Participation in this study will involve 7 study visits scheduled over a period of approximately 3 months and during this time a number of tests are carried out, these include physical examination including vital signs, blood, sputum and urine analysis, pulmonary function test and many more. We hope to recruit 3 patients.

- The purpose of this study is to evaluate efficacy and safety data for QGE031 (a new humanized monoclonal antibody directed against IgE) in patients with asthma and how well it compared to omalizumab (Xolair®) and placebo. The study will last up to 34 weeks and involve 12 visits and is looking to recruit approximately 460 worldwide. Our team is hoping to recruit 5 patients.

Clients

We have previous experience working on commercial and industrial drug trials focussing on respiratory health care. We have successfully facilitated CTIMP (Clinical Trials for Investigative Medicinal Products) for a variety of pharmaceutical clients in the past four years, providing quality research implementation. Previous clients include:

GlaxoSmithKline (GSK) (UK based, GSK is the 5th largest global healthcare company in the world (Since 2009))

Novartis (An international company based in Switzerland, Novartis is the 2nd largest seller of pharmaceuticals - 2010)
Novartis have used us numerous times for respiratory research, details of these completed studies can be seen on their study database here:
http://www.novctrd.com/ctrdWebApp/clinicaltrialrepository/public/products.jsp?divisionId=2&diseaseAreaID=9
Novartis have a fast-track path set up so that they can use our facilities repeatedly for their studies, because of our previous success and wonderful results.

Almirall (Spain's largest International pharmaceutical company). New twice a day bronchodilator in COPD.

Chiesi: developing a new bronchodilator combination in COPD.

AstraZeneca UK (British-Swedish pharmaceutical and Biologics Company headquartered in London, United Kingdom. It is the world's seventh-largest pharmaceutical company measured by 2009 prescription drug sales) we are currently involved in the study SIROCCO with AZ UK.

KaloBios study KB003-04 KaloBios is developing a robust proprietary portfolio of customized, targeted, first-in-class monoclonal antibodies designed to significantly improve the care of seriously ill patients with difficult to treat diseases.

Thanks to our ground-breaking research and success, Novartis has already set us up with a fast-track service, so our team can perform in all their COPD studies. We would like to invite and encourage other pharmaceutical and biotechnology companies to do the same.

Achievements

Throughout our five years of being involved in respiratory research we have many achievements to be proud of, these include:

Multiple Successes in acquiring a Global First Patient First Visit

First Patient First Visit (FPFV) is a vital target for a portfolio study to achieving order for the trial to proceed. Within 2 years of commencing clinical research we achieved a global first patient first visit in 2011. Since then we have repeated this feat for 3 successive years, between 2011 and 2013.

Multiple Chief Investigator Invitations

The Chief Investigator (CI) oversees and is accountable / responsible for all aspects of the trail. This includes its design, administration and operation, including managing and co-ordinating all Principle Investigators (PI) and sites.
Dr Saralaya has been invited to be Chief Investigator for two trials, this is a massive privilege and responsibility, as someone relatively new to research this is quite an achievement.

Consistent High Patient Recruitment and Retention

Recruiting patients in specialist areas can be challenging and time consuming, but it is vital that recruitment time and targets (RTT) are met efficiently. We have often been the highest recruiters on many trials in the UK and have been asked to recruit further patients to a trial to

enable the UK to reach its target. There is a stringent target from NHS acceptance to FPFV, first patient, first visit of thirty days; we have successfully met that RRT on multiple occasions.

Regular Contribution to the Community through e-Communications

it is important to us and mutually beneficial that researchers, patients and Trusts are continually informed. We are proud to say our progress and achievements have been reported in the Trust's magazine, the local Telegraph and Argus newspaper and even the Yorkshire Post. Not only does this inform patients and the public of our achievements but advertises respiratory research to all.

Meet the Team

Dr Dinesh Saralaya

Consultant respiratory physician & Honorary Senior Lecturer

Dr Saralaya graduated from India and completed his higher medical qualifications including his research both in India and in the UK. Dr Saralaya completed his speciality medical training in Yorkshire and has been a recipient of the British Lung Foundation travel fellowship in 2000. He has an interest in the management of severe asthma and COPD. He has pioneered the use of anti IgE therapy for severe allergic asthma and has been an author to several abstracts in international congresses on the real life effectiveness of anti IgE therapy in the UK. Dr Saralaya is lead clinician for respiratory medicine in Bradford and is also an Honorary Senior Lecturer at the University of Leeds. Recently Dr Saralaya has been appointed as Associate Director of Research, Bradford Institute of Health Research and the National deputy industry lead for respiratory medicine at NIHR.

Dr Abid Aziz

Consultant respiratory physician & Tutor for medical placement students

Dr Aziz qualified in Pakistan in 1996 and became a member of the Royal College of Physciancs (MRCP) in 2002. He has worked previously in Dewsbury District Hospital and St James University Hospital, Leeds. He became a Specialist Respiratory Registrar in 2003. After completing his specialist training on the

Dr Badie Jacob

Consultant respiratory physician & Honorary Senior Lecturer

Dr Jacob qualified in 1972 with his MB chB from Iraq, and in 1987 undertook an MD (Medical Research Degree) focussing in respiratory medicine and critical care, which he completed at the Yale School of Medicine, USA. He became a member for the Royal College of Physicans in 1982 and in 1987 was

Yorkshire specialist training rotation,he joined the respiratory team at Bradford as a consultant repiratory physician in 2009. He also tutors the medical students from Leeds . He is clinical governance lead for respiratory medicine and has pioneered the introduction of EBUS in Bradford.

awarded a fellowship (FRCP). He specialises in asbestos lung diesase, interstitial lung disease and TB.

Karen Regan

Respiratory research study coordinator

Karen is a registered nurse and has a respiratory background from working on an acute medical ward for many years. She has worked as the respiratory nurse specialist for 5 years before being a full time research nurse. Karen is working towards her master's degree and is also an independent prescriber.

Laura Walker

Respiratory Research Nurse

Laura is a registered nurse and has a respiratory background from working on an acute medical ward since she qualified. She worked on the ward for 4 years and has spent the past year working with Dr. Saralaya as a full time research nurse. Laura hopes to work towards been an independent prescriber in the future.

Nabeela Nazir-Ahmed

Respiratory Research Assistant

Nabeela joined the respiratory research team as an assistant and has been in this role for 3 years. She previously worked as a healthcare assistant on a medical admissions unit (MAU) for many years, gaining her NVQ 2 and 3 qualifications whilst working on the unit. She also ran an outpatient clinic on MAU where she gained skills such as phlebotomy, cannulation and ECG recording.

Stephen Cox

Respiratory Research Administrator

Stephen has worked for the NHS for 3 years; he has worked in cardiology, lung cancer and recently joined the respiratory research team as an administrator. His role is to keep our notes and records up to date, respond to emails and telephone calls regarding our trials and organise clinics. Stephen also arranges appointments for the group of asthma patients we treat that return for medication every two weeks. Stephen is currently being trained on how to enter data into electronic data capture sites.

Contact Us

Interested in getting involved with respiratory research?

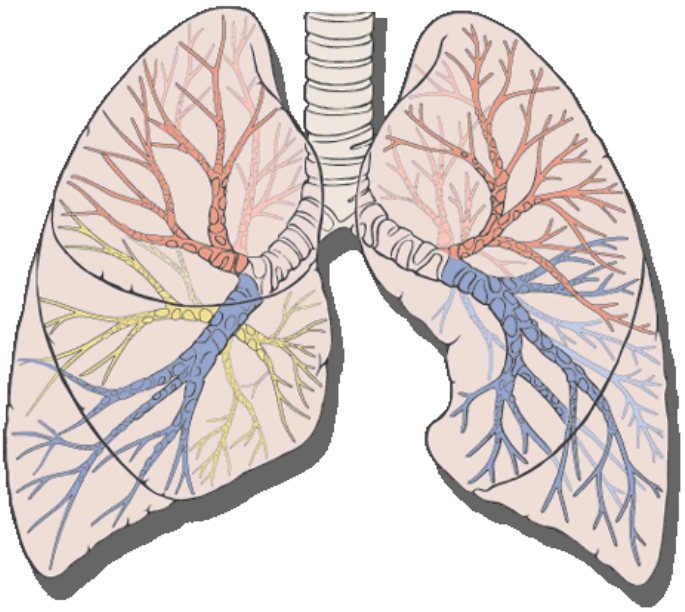
Contact **Stephen Cox** (our Research Administrator) in the first instance:
E: Stephen.cox@bthft.nhs.uk
P: **01274 383383**
M: **07903878821**

Need to get in touch with another member of our respiratory research team?

Dr Dinesh Saralaya (Consultant Respiratory Physician & Honorary Senior Lecturer) -	Dinesh.saralaya@bthft.nhs.uk
Karen Regan (Respiratory research study coordinator) -	Karen.regan@bthft.nhs.uk
Laura Walker (Respiratory Research Nurse) -	Laura.walker@bthft.nhs.uk
Nabeela Nazir-Ahmed (Respiratory Research Assistant)	Nabeela.nazir-ahmed@bthft.nhs.uk

Find out more about our facilities:

Our Respiratory Research Team's Website with the BTHT:



Interested in learning more about local research, support and facilities available in Yorkshire and Humber?

Official CRN Website and our Industry Specialisms:

NHS
National Institute for Health Research
Clinical Research Network

Want to Find us, Follow us, Connect with us and Contact us?

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