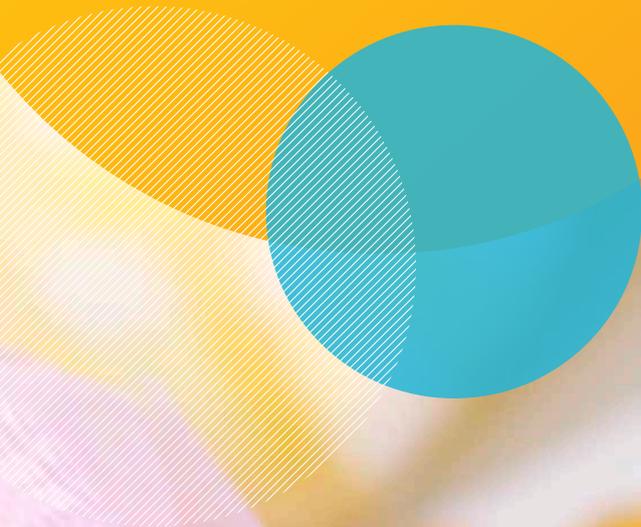
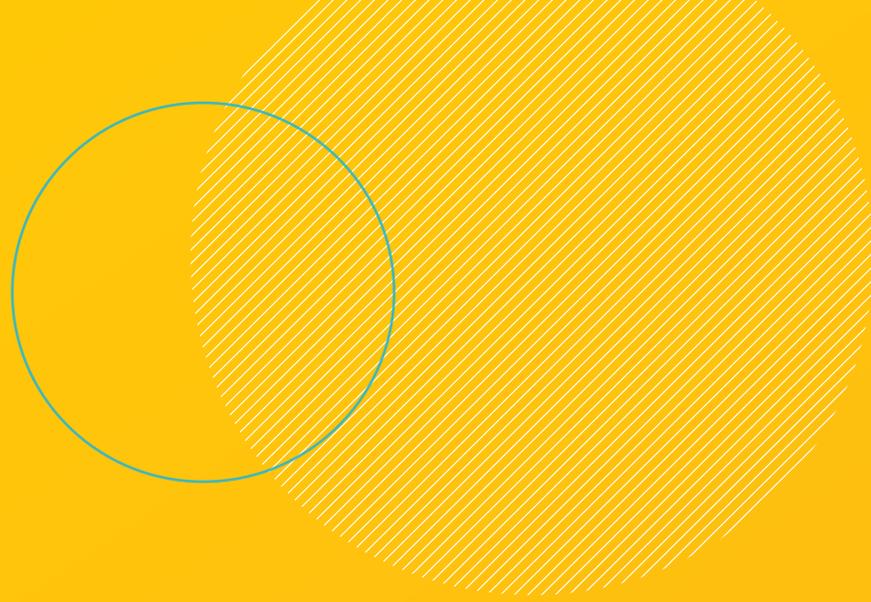


YOUR CLINICAL RESEARCH PARTNER

# ORAL CARE CLINICIAN OVERVIEW

Intertek Clinical Research Services





# Clinical Research Services: Our Clinical Expertise

Ensuring the safety and efficacy of your oral care products is critical to success. In an era where financial prudence is a necessity, getting your clinical, in vitro and analytical strategy right first time is more important than ever.

For the last 20 years, Intertek's Clinical Research Services group has been a trusted partner for organisations who develop and manufacture oral care products. We are now one of the world's largest providers of human testing in this area and have considerable experience in the recruitment and management of clinical trials. We provide Total Quality Assurance through risk-based approaches, delivering robust data to support the efficacy and safety of novel treatments, medical devices, medicines and cosmetics and help you meet your specific regulatory requirements through risk-based Good Clinical Practice (GCP) compliant approaches.

## **Our experience**

Our clinicians are able to provide a wide range of skills from study design, clinical examinations and clinical execution through to report generation. We offer a reliable solution for safety, product development, regulatory compliance and advertising claim support.

Our oral care clinical team are critical to the generation of robust data, all are qualified dentists, dental hygienists or therapists and have extensive experience in oral health care. We also have access to a wider pool of dental professionals and consultants to provide the experience and flexibility required to perform a successful clinical trial. Intertek understands the critical need for trained and experienced dental assessors to perform clinical assessments on studies. To this end, we maintain a pool of five fulltime examiners using indices to measure plaque, gingivitis, stain & whitening, dentinal hypersensitivity and oral tolerance. Our clinical assessors have experience in a number of clinical indices and are published in plaque removal, antimicrobial efficacy, gingivitis, malodour, sensitivity, whitening/stain removal, in situ remineralization and oral tolerance.

A full list of our publications can be found on our website: [intertek.com/beautypersonal-care/consumer-healthcare-trials-publications](https://www.intertek.com/beautypersonal-care/consumer-healthcare-trials-publications).

Intertek undertakes a structured and regular calibration program, giving assessors the opportunity to meet regularly and share skills when training. Through calibration exercises we ensure consistency amongst assessors and greater flexibility in resourcing studies. Our assessors are annually calibrated for the most commonly used indices, and are calibrated and /or familiarised prior to using any of the lesser known indices.

## **Total peace of mind**

By applying a risk-based approach we deliver a bespoke package which fits your requirements exactly, allowing a cost effective approach without any compromise in quality and ensuring compliance with relevant legislation.

Our specialists work with you at every stage of development and manufacturing, providing responsive, quality-compliant solutions. We respond precisely to your needs, going beyond just 'testing' to deliver Total Quality Assurance and peace of mind.



## Meet our team

### Robert Maclure BSc BDS



Robert Maclure joined the company in March 2012 and now fulfils the role of Medical Director, ensuring the safety and welfare of our volunteers and managing the training and calibration programme for oral care indices.

Robert acts as Principal Investigator (PI) and has been involved in a number of studies, including clinical trials of medicines and medical devices. He is experienced in the use of digital imaging systems including the QLF-D system and also in the design and execution of "in situ" enamel erosion studies.

Robert is published in the areas of tooth sensitivity, plaque removal and gingivitis. In addition Robert presented research investigating the clinical assessment of plaque using dental Loupes at the 45th American Association Dental Research (AADR) Annual Meeting in Los Angeles and chaired the Oral Health Research poster session. He is a member of the International Association Dental Research (IADR) and the British Dental Association.

He is trained and calibrated in the following indices:

- Modified Lobene Extrinsic Tooth Stain Index (Macpherson modification)
- Vita Shade (Classic and Bleached Guides)
- Gingival Margin Plaque Index of Harrap

- Modified Gingival Margin Plaque Index
- Modified Gingival Index of Lobene
- Gingival Bleeding Index of Ainamo and Bay
- Gingival Bleeding Index of Saxton and van der Ouderaa
- Gingival Index of Loe and Silness
- Quigley and Hein Plaque Index(Turesky and Lobene Modifications)
- Modified Navy Index (Rustogi Modification)
- Dentinal Hypersensitivity, tactile (Yeaple Probe) and evaporative air (Schiff Assessment)

Prior to joining Intertek Robert has worked in private and NHS dentistry in the UK and Czech Republic in addition to dental defence services in the UK and Germany.

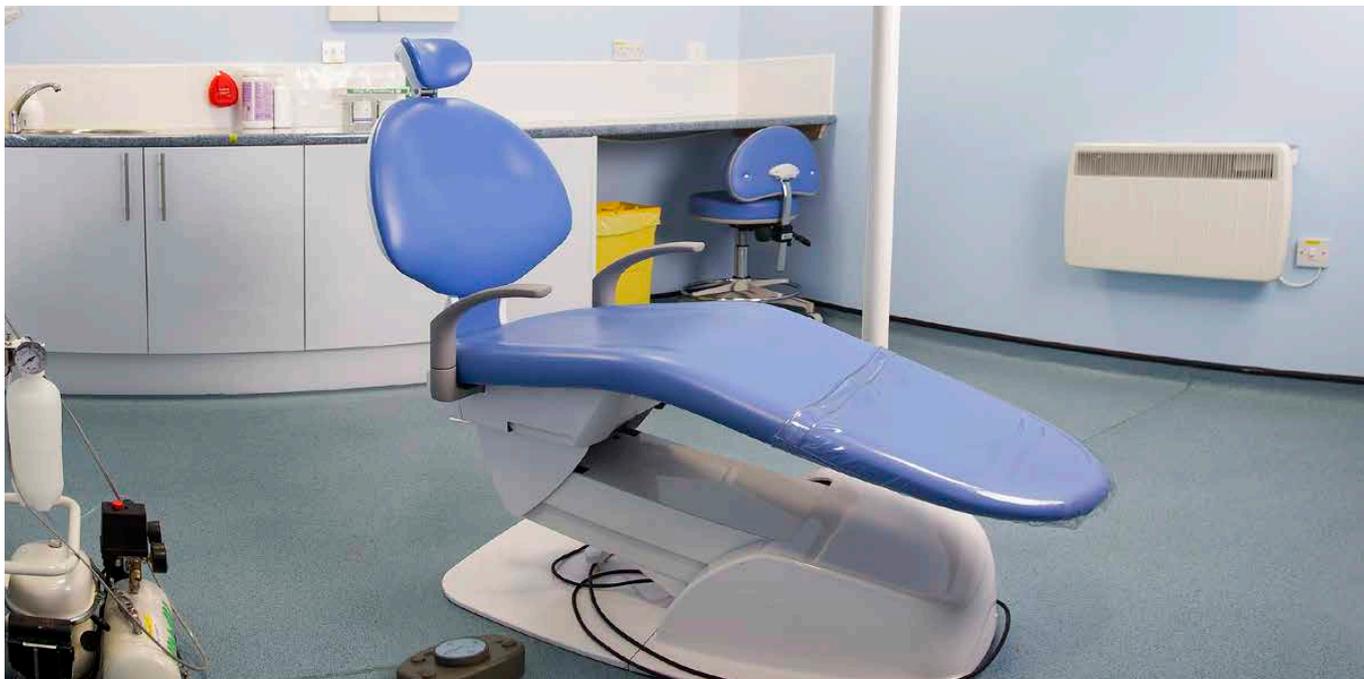
### Pavanjit Garcha (Consultant) BDS, MFDS RCS, MPH, DDPH RCS

Pavanjit Garcha acts as Principal Investigator and has been investigator or assessor on a number of studies including those involving medical devices. He is trained and calibrated in the following indices:

- Modified Lobene Extrinsic Tooth Stain Index (MacPherson Modification)
- Vita Shade (Classic and Bleached Guides)
- Gingival Margin Plaque Index of Harrap
- Modified Gingival Index of Lobene
- Dentinal Hypersensitivity, tactile (Yeaple Probe) and evaporative air (Schiff Assessment)

Prior to joining Intertek, Pavanjit worked in private and NHS dentistry in the UK and Canada and has lectured at Guy's Hospital, Kings and St Thomas' Hospital, London. He is particularly interested in cosmetic dentistry, and the use of dermal fillers in aesthetic dentistry.

We offer a reliable solution for safety, product development, regulatory compliance and advertising claim support.



**Jon Holt BDS (Consultant)**

Jon Holt has extensive experience in oral care clinical studies having worked in the field for over 20 years. He has worked with various oral care manufacturers and has consulted in the public domain with GSK, Unilever, Philips Oral Healthcare, Johnson and Johnson and Pfizer.

Jon has acted as Principal Investigator and/or assessor for over 230 studies including medicines and medical devices. His experience and publications covers plaque control, gingivitis and periodontitis, in situ caries, dentinal hypersensitivity, dental stain / tooth whitening and oral malodour. In addition to this he has experience in oral microbiology, herpetic lesions, salivary flow and pharmacokinetics. Jon has managed and led training courses for assessors around the world including India, China, USA, Ireland, Germany, France and the UK.

**David Payne BDS (Consultant)**

David has acted as Principal Investigator for Intertek since 2006. Prior to this David was a general dental practitioner for over 30 years. Although David is not a trained oral care assessor he provides medical support and dental expertise in a number of areas such as plaque control, malodour and gingivitis. David has been Principal Investigator on a number of studies including clinical trials of medicinal products and paediatric populations. He is also published in a number of areas, including plaque removal, antimicrobial treatments, malodour and tooth whitening.

By applying a risk-based approach to our services Intertek can deliver a bespoke package fitting your requirements allowing a cost effective approach without any loss in quality and ensuring compliance with applicable legislation.



**Jacqueline Cullen Mahon - Dental Care Professional EDH**

Jackie has been an oral care assessor for over 10 years and is now our Senior Clinician. She is an experienced,

calibrated assessor who has acted as an assessor/examiner using a number of indices/procedures. Jackie is trained and calibrated (as appropriate) in the following:

- Modified Lobene Extrinsic Tooth Stain (MacPherson Modification)
- Vita shade measurement (Classic and Bleached guides)
- Gingival Marginal Plaque Index of Harrap
- Modified Gingival Index of Lobene
- Modified Gingival Margin Plaque Index
- Gingival Bleeding Index of Ainamo and Bay
- Gingival Bleeding Index of Saxton and van der Ouderaa
- Gingival Index of Loe and Silness
- Quigley and Hein Plaque Index (Turesky and Lobene Modifications)
- Modified Navy Index (Rustogi Modification)
- Shade Assessments - Shade wave dental imaging system
- Sillness and Loe Plaque Index
- Volpe and Manhold Calculus Index
- Occlusal Fissure Plaque Index

Jackie also acts a project manager coordinating and managing clinical trials involving medicinal oral care products and medical devices and is published in tooth whitening and examination techniques.



**Fiona Moore - Dental Care Professional EDH/EDT**

Fiona Moore is a qualified dental therapist and has worked within clinical research for over 10 years. She

is an experienced, calibrated assessor who has acted as an assessor/examiner using a number of indices/procedures. Fiona is trained and calibrated (as appropriate) in the following:

- Modified Lobene Extrinsic Tooth Stain (MacPherson modification)
- Vita shade measurement (Classic and Bleached guides)
- Gingival Marginal Plaque Index of Harrap
- Modified Gingival Index of Lobene
- Modified Gingival Margin Plaque Index
- Gingival Bleeding Index of Saxton and van der Ouderaa
- Gingival Bleeding Index of Ainamo and Bay
- Gingival Index of Loe and Silness
- Quigley and Hein Plaque Index (Turesky and Lobene Modifications)
- Modified Navy Plaque Index (Rustogi Modification)
- Silness and Loe Plaque Index
- Volpe and Manhold Calculus Index
- Occlusal Fissure Plaque Index

Fiona's experience in assessing plaque and gingivitis has been published in the International Dental Journal and presented at the 2014 and 2016 AADR conferences.



**Patricia Rimmer - Dental Care Professional EDH**

Patricia has been an oral care assessor for over 10 years. She is an experienced, calibrated assessor

using a number of indices/procedures. Patricia is trained and calibrated in the following:

- Modified Lobene Extrinsic Stain Index
- Vita Shade Assessment (Classic and Bleached guides)
- Gingival Marginal Plaque Index of Harrap
- Modified Gingival Index of Lobene
- Modified Gingival Margin Plaque Index
- Gingival Bleeding Index of Ainamo and Bay
- Gingival Bleeding Index of Saxton and van der Ouderaa
- Gingival Index of Loe and Silness
- Quigley and Hein Plaque Index (Turesky and Lobene Modifications)
- Modified Navy Plaque Index (Rustogi Modification)
- Shade Assessments - Shade wave dental imaging system
- Silness and Loe Plaque Index
- Volpe and Manhold Calculus Index
- Occlusal Fissure Plaque Index

Patricia also acts a study coordinator running the day to day activities of clinical trials. She has experience of running a number of trials involving oral care products and therefore has a wide range of skills and capabilities. Patricia's work in the assessment of dental plaque has been published in a number of dental journals including International Journal of Paediatric Dentistry and the British Dental Journal, her work has been presented at 2013 IADR conference 2016 AADR conference.



**Emma Speed-Dental Care Professional EDH**

Emma has now been and oral care assessor for the past 3 years. Emma has successfully calibrated against

our experienced assessors and manages the Intertek oral care calibration programme. She is trained and calibrated (as appropriate) in the indices/ procedures below:

- Modified Lobene Extrinsic Stain Index
- Vita Shade Assessment (Classic and Bleached guides)
- Gingival Marginal Plaque Index of Harrap
- Modified Gingival Index of Lobene
- Modified Gingival Margin Plaque Index
- Gingival Bleeding Index of Saxton and van der Ouderaa
- Quigley and Hein Plaque Index (Turesky and Lobene Modifications)
- Modified Navy Plaque Index (Rustogi Modification)
- Shade Assessments - MHT Spectroshade

APPENDIX 1: Weighted Kappa Values For the Recent Examiner Calibrations - BDS		
	R.Maclure	P. Garcha
Modified Quigley and Hein Plaque Index	0.8622	0.8549
Modified Lobene Tooth Stain (MacPherson modification)	0.8681 Intensity 0.8776 Area	0.7105 Intensity 0.7207 Area
Gingival Marginal Plaque Index of Harrap	0.8906	0.9147
Modified Navy Plaque Index (Rustogi Modification)	0.7960 (Buccal) 0.7448 (Lingual)	NA
Modified Gingival Index of Lobene	0.8129	NA
Vita shade measurement (Classic)	0.9702 (Classic) 0.9713 (Bleached)	1.0000 [Classic] 0.9452 (Bleached)

APPENDIX 1: Weighted Kappa Values For the recent Examiner Calibrations - Dental Care Professionals - RDH/RDT				
	F.Moore	P.Rimmer	J.Cullen Mahon	E.Speed
Modified Quigley and Hein Plaque Index	0.8670	0.8188	0.9043	0.8486
Modified Lobene Tooth Stain (MacPherson modification)	0.7935 (Intensity) 0.7833(Area)	0.7582 (Intensity) 0.7545 (Area)	0.9035 (Intensity) 0.8886 (Area)	0.8439 (Intensity) 0.8191 (Area)
Gingival Marginal Plaque Index of Harrap	0.9050	0.9237	0.9421	0.9240
Modified Navy Plaque Index (Rustogi Modification)	0.7758 (Buccal) 0.7308 (Lingual)	NA	0.8203 (Buccal) 0.7953 (Lingual)	NA
Modified Gingival Index of Lobene	0.6696	0.8213	0.7640	0.7485
Vita shade measurement (Classic)	0.9939 (Classic) 0.09615 (Bleached)	0.9592 (Classic) 0.9300 (Bleached)	1.000 (Classic) 0.9753 (Bleached)	1.0000 (Classic) 0.9954 (Bleached)





---

Intertek Clinical Research Services  
Elm House, Unit A4  
Oaklands Office Park  
Hooton Road  
Hooton  
Cheshire CH66 7NZ  
UK

 +44 151 347 4810

 [clinicalresearch@intertek.com](mailto:clinicalresearch@intertek.com)

 [intertek.com/crs](http://intertek.com/crs)