

DEVELOPMENT SUPPORT

ORAL CARE RESEARCH SERVICES

Intertek Clinical Research Services

Oral Care Product Services

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.

We understand the need to have a responsive, flexible testing resource, with experienced project management to meet your critical milestones and deliver robust data every time. Intertek's Clinical Research Services group has been a trusted partner for those manufacturing oral care products and is now one of the world's largest CROs for the provision of human trials in this area.

Supporting your R&D, Regulatory and Claim Support needs:

- Clinical Studies
- In Vitro Performance Testing
- Bioanalytical Services
- Analytical Services
- Auditing and Assurance
- Regulatory Support

We have considerable experience with the recruitment and management of clinical trials. Our clinical capabilities support the full clinical trial life-cycle, including protocol development, ethical review, participant recruitment, full study management, data management, statistical analysis and reporting. We provide robust data to support the efficacy and safety of oral care products and can generate claim support and marketing data to meet tight product launch deadlines.

Our laboratory facilities also provide comprehensive in vitro and bioanalytical solutions for these specialised products, helping you to navigate the challenges of development, testing, regulatory authorisation and manufacturing.

Achieving Total Quality Assurance

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.

Our specialists work with you at every stage of development and manufacturing, providing responsive, quality-compliant solutions. We respond precisely to your needs with solutions that go beyond just "testing" to help you achieve total quality assurance, offering total customer peace of mind.

Our Capabilities

<p>Subject Recruitment</p>	<p>Intertek’s clinical research group maintains a database of pre-qualified participants. This cloud based application allows the efficient management and monitoring of participants. Key data such as oral health conditions (e.g. dental hypersensitivity), cosmetic concerns (e.g. tooth stain), demographics and habits (e.g. dental product use) is captured to allow effective searches to be conducted, therefore reducing recruitment time and cost, as well as improving qualification rates.</p>
<p>Dental Examiners</p>	<p>We understand the critical need for trained and experienced examiners to perform clinical assessments on studies. To this end, Intertek maintains a pool of examiners using indices to measure plaque, gingivitis, stain & whitening, dental hypersensitivity and oral tolerance. Our experts conduct over 35 oral care clinical studies per year, which means that examiners’ assessment skills are utilised regularly throughout the year.</p> <p>With structured and regular training and calibration program, our examiners have the opportunity to meet regularly and share skills. Through calibration exercises we ensure consistency amongst assessors and greater flexibility in resourcing studies.</p> <p>Our experienced dental clinicians establish a robust evidence base for a dental treatment and, in particular, support your clinical trials of new medicines, consumer healthcare products and medical devices which are being developed to treat conditions and diseases that affect the teeth and gums and other oral tissues. We apply efficient and appropriate approaches to trial methodology for dental research applications working to all applicable clinical trial legislative guidelines including ISO14155 Clinical Investigation of Medical Devices.</p>
<p>Clinical Facilities</p>	<p>Each Intertek clinical research site offers the optimal blend of practicality and flexibility. As such all sites offer the capability to accommodate studies in different indications, with a balance of clinical rooms made up of oral care surgeries, private examination rooms, interview areas and sample preparation areas. Additional general facilities at sites include:</p> <ul style="list-style-type: none"> • Secure, temperature monitored test product storage • Emergency resuscitation equipment • Fire-proof storage for trial documents <p>Intertek’s systems and procedures have the flexibility to provide a tailored service for both regulated and cosmetic products and our operations have been inspected for GCP by local regulatory authorities.</p>
<p>Standards of Service</p>	<p>Whether your product falls within cosmetics, medicines or medical device regulations you can be assured that Intertek will comply with all legal and ethical guidelines for clinical testing. Intertek complies with Good Clinical Practice (GCP), UK medicines regulations, ISO 14155 and COLIPA guidelines.</p> <p>For cosmetics a tailored service can be provided based on trial complexity and risk. Key aspects of GCP can be applied; however the safety and wellbeing of the participants will never be compromised.</p>
<p>Auditing and Assurance Services</p>	<p>We apply a systemic approach to supporting our customers’ Quality Assurance efforts in each of the areas of their operations including R&D, raw materials sourcing, manufacturing, transportation, distribution and retail channels. Our global network of auditors and technical experts are dedicated to helping you meet any auditing or certification challenge you may face. Services include:</p> <ul style="list-style-type: none"> • Good Clinical Practice compliance audits • Clinical Investigator site qualification audits • Global supply chain • Accreditations: <ul style="list-style-type: none"> ◦ ISO 13485:2003 Medical Management System ◦ ISO 22716 Good Manufacturing Practices ◦ ISO 13485:2016 Quality Management Systems for Medical Devices ◦ ISO 9001 Quality Management
<p>Bioanalytical Services</p>	<p>With a network of technical, specialized partners Intertek can provide quantitative measures of active compounds in biological fluids, specifically saliva, plaque and gingival circular fluid. In this way we can support pharmacokinetic studies, investigate bioequivalence and identify key protein markers for oral care conditions. Techniques include:</p> <ul style="list-style-type: none"> • Chromatographic method such as HPLC and GC • Electrophoresis • Ligand binding assays such as ELISA • Mass spectrometry • Nuclear magnetic resonance
<p>Analytical R&D Support</p>	<p>Outside of your clinical programme, Intertek can provide the following services to assist with your product development:</p> <ul style="list-style-type: none"> • Product – substrate interactions - Examination of active delivery and product efficacy • Product characterisation - This includes de-formulation, physical specifications and active ingredient • Quantification • Product safety - Assessments of contaminants / prohibited materials assessment, as well as stability studies and microbiological control



Clinical Research Services

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Dental Plaque

Dental plaque is considered to be a key aetiological factor in caries and gingivitis. Our assessors are familiar with a number of indices and their modifications, including Quigley & Hein, Silness & Loe and Navy to name a few. Additionally, we regularly conduct plaque sampling and analysis (microbiology, active agent deposition etc).

Stain Removal and Whitening

The pursuit of a bright, white smile has led to an explosion of stain control and whitening products. We have experience of the MHT SpectroShade and considerable experience of a number of protocols incorporating the Lobene tooth stain index, (MacPherson modification), Vita shade, (bleached and classic) and artificial stain build up.

Gingivitis

Sub-optimal oral hygiene may lead to gingivitis and a number of products aim to control this condition. We have experience of a number of study designs from 21 day, through to six months and are experienced in several indices including Gingival Index, Modified Gingival Index and Bleeding indices. Gingival Crevicular fluid sampling and elution can be conducted as required.

Dental Sensitivity

Dentinal hypersensitivity is a common and painful condition. Accurate diagnosis of the cause of any painful stimuli to exclude non-dentinal hypersensitivity aetiologies is key to running successful clinical trials in this area. Examples of indices used are evaporative air (Schiff) and tactile stimuli using a Yeaple Probe, of which we own a number.

Malodour

Control of bad breath has been identified as a key consumer need. Intertek CRS has wide experience of instrumental measurements of malodour using Gas Chromatography and Oral Chroma.

Caries & Erosion

Intertek has experience in a number of in-situ models designed to assess the changes in enamel and dentine hardness. The Intertek laboratory are able to prepare bovine and human specimens for use in in-situ models or cycling models and use surface microhardness to assess hardness of the tooth structure. This is a good example of where the clinical / laboratory relationship is key to success.

Calculus

The removal of calculus remains the preserve of the dentist and hygienist. Controlling build up of calculus by both chemotherapeutic and mechanical means can be measured using the Volpe-Manhold Index - an index with which our assessors are familiar.

Dental Abrasivity

We have an in-situ model which allows assessment of enamel and dentine abrasion on real dental tissue. Example methodologies are in-situ enamel wear, in-situ dentine wear and in vivo toothbrush abrasion (soft tissue).

Oral Tolerance

Intertek offers bespoke clinical studies to assess the safety and acceptability of oral care products on the oral soft and hard tissues.

Consumer Perception

Feedback from members of the public can be critical in the product development process. To this end, Intertek can offer self-perception questionnaires, focus groups, interviews and home-placement studies.



A full list of our publications can be found on our website [intertek.com/crs](https://www.intertek.com/crs)



In Vitro Research Services

Intertek has a team of dedicated analysts and multi-disciplinary scientists able to assist with a variety of in vitro oral care studies

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Hard Tissue Preparation

Intertek can assist you with your own laboratory studies through the provision of human and bovine hard tissue samples (enamel or dentine) or hydroxyapatite samples. Discs or blocks can be supplied to any specification and finish, using a wide range of specialized equipment.

Anti-stain

We offer artificial stain build-up protocols utilizing human or bovine enamel blocks. Artificial staining solutions typically contain tea, coffee, red wine and/or tobacco extract and can be formulated according to published methods or be specifically blended to the client's requirements. Stain assessments can be carried out at various time points using a colorimeter.

Anti-calculus

Anti-calculus testing is offered for mouthwash and toothpaste products. Plaque is seeded from pooled human saliva and grown on Perspex rods. These are then cycled between test products, human saliva and mineralizing solutions containing calcium. Plaque is harvested, weighed and analysed for calcium using ICP-OES.

Dental abrasivity

Intertek offers both 2-D and 3-D surface profilometry to measure abrasion, roughness, and tissue loss from dentine and enamel blocks.

Caries

Artificial lesions can be prepared in enamel or dentine blocks using acid solutions or gels. The blocks are then subjected to pH cycling protocols followed by microhardness or microradiography evaluation.

Cleaning Efficacy

We offer cleaning evaluation of dentifrices, toothbrushes, interdental brushes, flosses and tapes. Intertek has a bespoke artificial brushing machine that can be used for abrasivity and pellicle cleaning ratio (PCR) testing.

Enamel Erosion

Erosion of enamel by acidic drinks or foods is of increasing concern to consumers. We can test your product's efficacy at preventing or treating this issue.

Scanning Electron Microscopy (SEM)

We can now offer scanning electron microscopy enabling you to visualize enamel or dentine surfaces to a high degree of magnification. This is particularly useful for observing dentin tubule occlusion or analysing repaired enamel. Our instrument also has the ability to perform EDS X-ray elemental analysis enhancing its investigative capabilities.





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

 intertek.com/oral-care