WHITE PAPER

ACCELERATING ORAL CARE PRODUCT DEVELOPMENT

PART 1 - PARTNERSHIP WITH *IN VITRO* ASSESSMENT EXPERTS

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INTRODUCTION

Innovation is a core focus for science-led developers of oral care products. Significant challenges, however, can be associated with available resources, timelines and meeting the evolving demands of consumers for safe and effective products.

Successful formulation and launch of new oral care products requires marketing claims which are supported by robust scientific evidence. *In vivo* human clinical studies for oral care products are the gold standard in terms of product assessment, involving a large panel of volunteers.

CLINICAL STUDIES: CONSIDERATIONS AND CHALLENGES

Clinical studies of oral care products have evolved over the past several decades and now constitute an established science, with many clinical study designs published in peer-reviewed journals. Test protocols have become accepted models, which are accepted industry-wide. Typical clinical indices include those in Table 1. A good example is the plaque index, where a tooth is stained with suitable dye and scored against a suitable index by a trained assessor, usually a dentist or dental hygienist. There are several variations of this model, all with pros and cons, such as the Quigley and Hinds Index. A chosen variable will, generally, be measured at baseline, then reassessed after a day or several weeks of blinded product use. Differences in mean scores will be calculated statistically and assessed for clinical relevance.

Table 1: Clinical indices useful in oral care product development

Clinical Indices	Model
Plaque	Q&H & modifications, Navy
Stain	Lobene
Colour/shade	VITA Shade
Dentinal hypersensitivity	Schiff, Yeaple probe
Gingivitis	MGI, GI, bleeding

The advantages of clinical testing are obvious: products are tested under real-use conditions, and the measured benefits are, therefore, quantitatively meaningful and can lead to scientifically supported marketing claims.

A major disadvantage of clinical testing is the expense involved. This is particularly when considering a statistically designed clinical trial lasting six months or more, which require a large number of volunteer subjects. These studies need to be conducted by highly skilled medical professionals with assessors who must undergo regular calibration and training. The number of specialist contract research organizations (CROs) who can perform these are limited and are not likely to be available in all countries. Such studies are, also, likely to be moderately invasive to the subject, must be run to Good Clinical Practice (GCP) standards, and require prior ethical clearance. All these factors impact total cost and demand on resources. Overall, it should be noted that the variability in population response could mean that the outcome of even a robustly controlled study might not deliver the desired outcome for the sponsor. This is particularly frustrating where subject compliance is a significant issue.

BENEFITS OF *IN VITRO* LABORATORY STUDIES

An alternative approach is to perform *in vitro* laboratory testing. A well-designed *in vitro* test can often yield the required data much more quickly, and at a lower cost, compared to clinical studies. Owing to the *in vitro* nature of these studies, there is no possibility of harming a volunteer subject. Variability of response tends to be better controlled, as it is much easier to control product exposure and treatment conditions in a laboratory-based procedure as opposed to entrusting a panel of subjects to follow a set of instructions at home. Low turn-around times to design and implement an *in vitro* study mean that results can provide better insight during formulation development, including early Proof of Principle stages. Successive iterations and statistical data analysis can guide early prototypes quickly to a stage where they are ready for clinical testing.

Data from *in vitro* studies can also be used for elementary marketing claim support, providing that results are appropriately qualified. This is particularly true with studies involving dentine abrasivity or stain removal. When carried out by a third party, they can be used as evidence of independent testing, which can be useful when marketing a product to trade and large retailers such as supermarkets. This data can also be used to defend challenges that may be taken up with advertising standard authorities. Other applications could provide independent reassurance of product efficacy or safety. While there are many advantages of laboratory-based studies, a caveat remains that the results do not necessarily translate into clinical efficacy, and that certain claims of timebound efficacy can be difficult to establish.

To achieve successful development and launch of multi-claim oral care products, it is necessary for the formulator to use a variety of different ingredients and iterations. This can place several demands on the development process.

Outsourcing of non-core support services is an established concept in many areas of modern development production. This is not uncommon in healthcare sectors, where all functions regarded as 'strategic but not core' are in scope for outsourcing, including laboratory services. Historically, laboratory testing services, to help drive corporate innovation with measurement and analytical data, were perceived as necessary to remain 'in-house'. Today, while the need to innovate remains more 'strategic and core' than ever, it is no longer the case that laboratory testing and measurement support need be.

Outsourcing *in vitro* laboratory testing services to a dedicated service provider can deliver time and cost savings. It can also offer strategic commercial benefit to the sponsor company, through robust testing programs conducted by experienced and skilled technicians who can drive insight and support for innovation while also providing an independent assessment of product efficacy.

Most importantly, working with a specialist laboratory outsourcing partner for *in vitro* services helps increase corporate market agility for responsiveness in today's fast moving and international marketplace and evolving consumer demands.

INTERTEK – A SPECIALIST *IN VITRO* TESTING PARTNER

Supporting your product development and claim substantiation

Our *in vitro* team has been a trusted partner for those companies developing and manufacturing oral care products for over twenty years. Today, it is a leading specialist service provider in the oral care sector offering *in vitro* method development, bespoke models and rigorous screening of oral care products, product development, regulatory compliance and advertising claim support.

Your core focus will be to deliver differentiated, high-quality consumer healthcare products, and you will need a strategic partner who invests in scientific and technical excellence to help you to develop and launch a pipeline of new products that meet the needs of buyers and consumers. At Intertek, we provide expertise to cover all main product development projects across toothpastes, mouthwashes, tablets, toothbrushes, interdental brushes, whitening kits, delivery systems, novel cleaning devices and marketing claim areas, including:

- *In vitro* models of cleaning efficacy
- Stain prevention / stain removal
- Abrasivity, tooth sensitivity, enamel erosion
- Remineralisation / demineralisation testing
- Scanning Electron Microscopy (SEM)
- Anti-plaque and anti-calculus

Our purpose-led vision is to make the world a better and safer place and to be the world's most trusted partner for Quality Assurance. Engage with us now to discuss how *in vitro* approaches to oral care product efficacy assessment can help accelerate your product development.

Access our Case Study Library:

Learn how *in vitro* studies can deliver data and insight on product efficacy and performance by requesting our case studies. One of our representatives will email these to you in the near future.

Request our Case Studies

- Benchmarking Anti-Plaque Agents In Dentifrices And Mouthwashes
- The Impact of a Toothpaste pH-Buffering System on Dental Plaque pH
- The Effect of Foods, Drinks or Pharmaceuticals on Teeth Colouration
- Dentine and Enamel Block Preparation
- Dentine Tubule Occlusion Studies
- Measuring Tooth Demineralisation and Remineralisation *In Vitro*
- Teeth Whitening 1 - Evaluating the Stain Removal Efficacy of Toothpastes using the PCR Model
- Teeth Whitening 2 - Efficacy Of A Teeth Whitening Treatment – "X Shades Whiter"

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Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 46,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

Meet the author

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Gavin has over 15 years of experience working within the *in vitro* oral care sector. He is currently the Laboratory Manager at Intertek Clinical Research Services and leads Intertek's team of scientists delivering a variety of *in vitro* methodologies for product evaluation and claim support, including enamel remineralisation, stain prevention/ removal and chemical whitening.

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