White Paper

Virtual real-world research: The new normal for consumer health claims generation

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Introduction

The increasing presence of digital technologies and communications, artificial intelligence (AI) / machine learning and big data analysis in our daily lives is blurring the lines between physical, digital and biological systems. Consumers, increasingly engaged in their own health and wellness journeys, are already enjoying growing support from digital technologies. This includes giving access to health information and advice via digital devices, advanced diagnostic tools, health and fitness tracking apps and wearables paired with AI. Consumers are also becoming more open to sharing their health data, personal preferences, knowledge and experience via digital media, leading to a new kind of relationship between consumers, healthcare specialists and the consumer health industry. Access to health tools and information has changed the perspective of consumers with regard to their healthcare, motivating them to do more "self-care."

Because consumers live such digitized lives, they have high expectations of the digital support they will receive when participating in a clinical trial, no matter the type. It is in part for this reason that consumer health trials driven through digital technologies are so well received. Since they tend to be more consumer centric, digital trial technology and services have created a spectrum of new clinical trial models, including entirely virtual ones, which effectively remove most of the labour-intensive inefficiencies of traditional trials. Data collected in the real-world context from consumers participating in their daily life situations is revealing new insights into perceived product benefits. Such data can be used to generate new type of claims.

In this whitepaper we will explore how virtual real-world research is different from established methods and why it will become the new normal for claims generation in Consumer Health.

"personal health maintenance to improve or restore health and to treat preventative diseases"

— World Health Organization (WHO)[1]

Why claims matter

In a crowded and competitive consumer health market, claims are a key communication tool to highlight a product's values and benefits to customers and consumers, whether on-pack or in marketing and promotional materials.

A claim may only be a few short words, but it is a crucial opportunity to explain the benefits of a product vs. other offerings. Health and efficacy related claims derive mainly from controlled clinical trials that follow generally recognized procedures. They need to be approved usually by regulatory authorities what underlines their credibility. Commercial messages such as "No 1 recommended product", packaging and format advantages like "take without water", or science-driven efficacy benefits such a "works faster" are also important ways to convince consumers to purchase.

These typical promotional claims are most often generated from marketing data and comparative clinical studies which somewhat homogenize the consumer experience. However, claims which are generated based on real-world data studies are different in that they more directly integrate the consumer perspective. Examples would be "90% of the consumers experience pain relief within 30 min after product intake" or "8 out of 10 consumers report a significant quality of life improvement". Despite the potential power of such claims derived from real-world context, "consumer to consumer" claims have been under-leveraged for consumer health products.

Of course, any on-pack or marketing material claim must be true and well substantiated, which is why it is vital to have robust strategies in place to develop strong evidence to back it up.

HELPING CONSUMERS NAVIGATE THE MARKET

Of course, claims can help position a product ahead of its rivals, but they also serve consumers. In a crowded and noisy consumer health market dominated by me-too products, a claim can act as tool to find the right product for a specific need. The more trust a claim engenders, the more confident consumers will be that they have found the best product for them. This underlines the value of integrating real-world claims derived directly from consumers rather than from manufacturer-based controlled clinical studies. Claims built on real experiences vs controlled clinical studies can serve as a bridge to consumers, helping them to better understand the benefits and make the best purchase decisions.

In a world where the proliferation of information has made consumers more health-literate than ever before, traditional research methods are no longer always delivering the clear and substantiated claims that can best help them to tackle their specific healthcare needs easily and safely. The good news is that there are powerful new tools available to help companies uncover need-derived claims, substantiate them so they pass regulatory and legal hurdles and build trust with savvy healthcare consumers.

Why a 'new normal' for consumer health claims generation?

Across the consumer health industry, established methods such as randomized clinical trials (RCTs) are still the primary method for developing new product claims.

However, RCTs are expensive and time consuming. In a business environment where high margins are expected, it is becoming increasingly difficult for companies to justify continual investment in RCTs to develop evidence to prove their efficacy (see Exhibit 1).

There is an efficacy – effectiveness gap[2] for most consumer health products. Efficacy describes how a product performs in an idealized or controlled setting (typically a controlled clinical trial) while effectiveness describes how medication is used in a real-world setting where patient populations and other variables cannot be controlled.

While data generated under well-controlled clinical trial conditions (selected subjects, strong control over usage of products and usage etc.) are considered to be the gold-standard in the hierarchy of evidence generation, alternative methodologies, standards and forms of evidence are growing in acceptance.[3,4]

Data generated under real-world settings, where the consumer applies and uses the product in uncontrolled and unguided conditions, can lead to novel insights and product benefits. Both types of studies undoubtedly have their place and address different questions. The efficacy-effectiveness gap may be even more prominent in the consumer health area than in Rx, where products are applied by or under the guidance of healthcare professionals (HCPs) under conditions much closer to RCT conditions than in a consumer health world.

Yet this reluctance to undertake such studies is playing out in a marketplace where consumers and regulators are demanding more evidence of value, efficacy and safety than ever before. Thus, the growing importance of data-driven, scientifically valid claims to gain consumer trust in the crowded me-too field of consumer health.

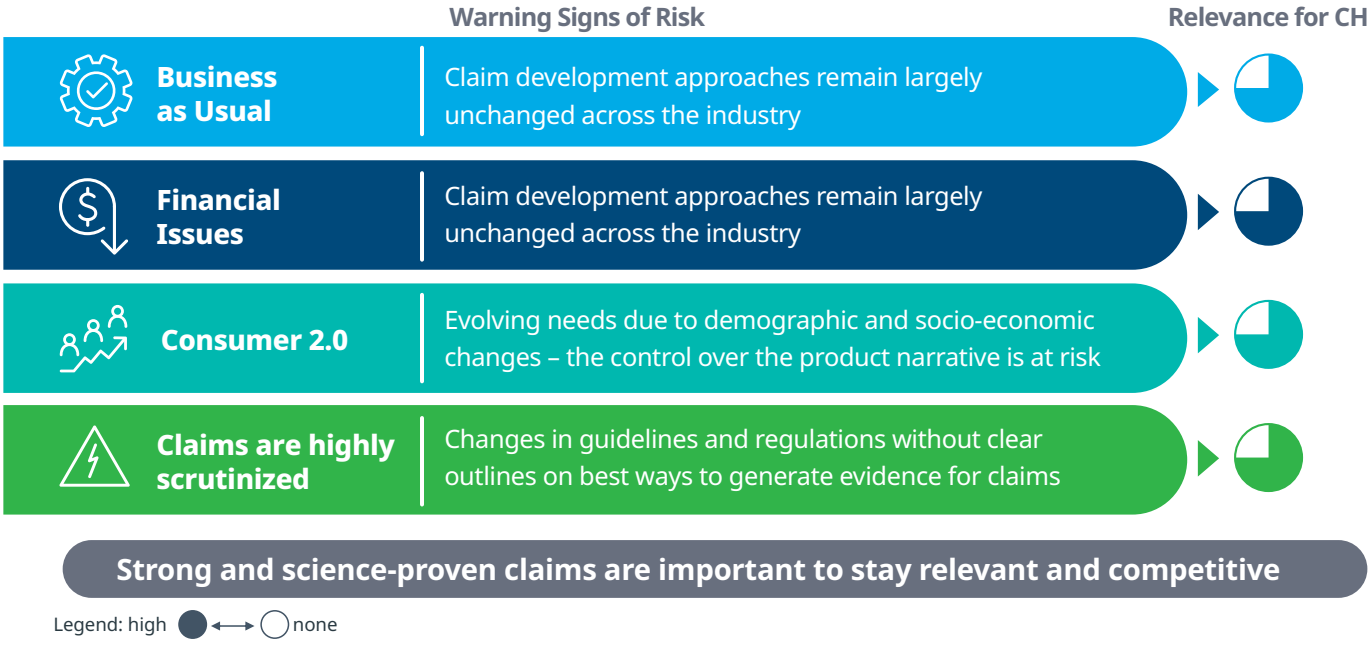
The days where companies could boost their sales with slick mass-media ads are gone. Today's Consumer 2.0 is much more involved in his/her own self-care and is more willing to seek out information to validate whether product-related messages are true. This shift in consumer behaviour, coupled with the explosion of online platforms that enable consumers to share their experiences with and perceptions of a brand, means that the product narrative can quickly and easily be diverted away from manufacturers. Collecting real-world data from consumers not only helps claims generation, but also delivers new insights in a dynamic and interactive way.

"Today's Consumer 2.0 is much more involved in his/her own self-care and is more willing to seek out information to validate whether product-related messages are true."

The shifting regulatory environment is another reason consumer-health companies are increasingly turning to real world data. Claims are increasingly scrutinized by regulatory and legal authorities.

Consumer health encompasses many regulatory categories with evolving guidelines for each, often varying by country or region. This presents a significant challenge: traditionally risk adverse companies must make strategic decisions on research priorities without a clear approved regulatory claim path. Since the environment is more regulatory push than pull, taking the risk to cost effectively generate high quality data for future regulatory lobbying and argumentation makes increasing sense.

Exhibit 1: Key Challenges to consumer health claims development (Source: IQVIA Consumer Health)



Industry views on consumer health claims generation

Findings of a survey carried out by IQVIA Consumer Health point to two key reasons for conducting trials. The primary reason is foundational - to gain a deeper understanding of consumers (33%). The second is more directed - the generation of data to support marketing claims (17%). Interestingly, the generation of real-world evidence (RWE) comes in a close third at 15% (see Exhibit 2).

When asked about the challenges of conducting research for consumer health claims, respondents find it most difficult to generate robust data to support the claims they want to make. They also struggle to justify the cost of the research. (see Exhibit 3). This suggests that many companies are probably still using traditional costly approaches that make larger samples sizes prohibitive.

Exhibit 2: Key reasons for carrying out consumer and clinical consumer health research (Source: IQVIA Consumer Health)

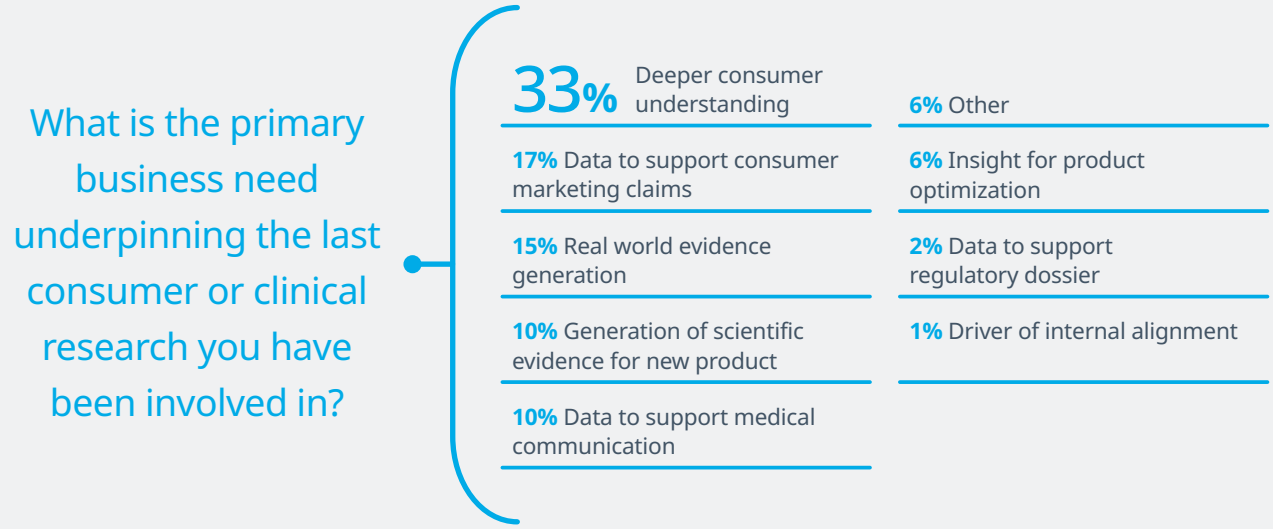
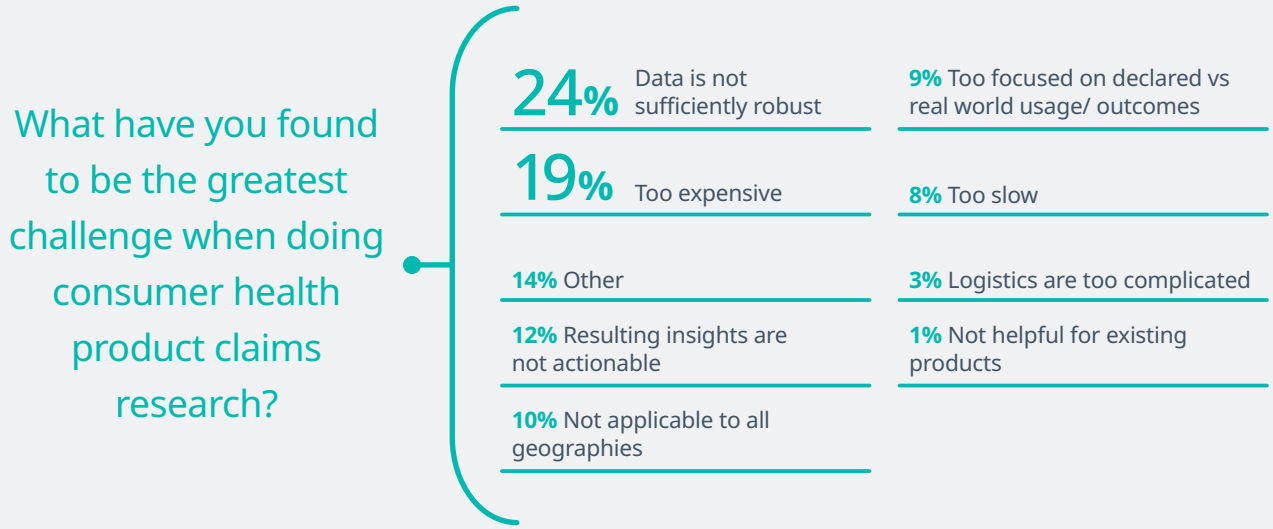


Exhibit 3: Greatest challenges to carrying out consumer health product claims research (Source: IQVIA Consumer Health)



When talking about claims development and substantiation of claims, we are mainly using the same mechanisms and ways of working as we have done over the previous 10 to 20 years. While these approaches aren't incorrect and provide robust scientific backing for claims, they are not always the best and ideal way of doing things.

The reason why we are using traditional methods is that it they have been proven to be robust and are broadly accepted. However, there may be new ways which are equally robust, and more agile and consumer-centric. The only caveat to this is that such ways of working are new; they have not been proven to work thousands of times and when done for the first time they bear a certain risk that one needs to be willing to take.

On the other hand, they represent the innovations we are always looking for and talking about. Innovation exists not only within the new products we deliver, but also in developing new ways of working and generating data. In this case, the data which substantiates our claims.

However, it is important to differentiate between 'label claims' and 'communication claims'. For communication claims, the goal is to have robust substantiation using methodologies which are different from the big, time and cost-intensive clinical studies. The current gold standard, developed for Rx and the only accepted one for label claims at present, is a RCT. With authorities becoming more open and releasing more guidance's on RWE/Real-World Data (RWD), the near future may present the opportunity to use more robust data from RWD studies to support label claims.

DR ANDREAS EHRET
Director, Clinical Development Services,
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Over the past ten years, things have changed in terms of how we carry out research for claims, and these provide many new opportunities for the healthcare industry as a whole, although, to date, they have been adopted more readily by the Rx side of the industry. The two most significant changes are:

- Regulators having changed their views on evidence generated by remote controlled studies, real-world evidence (RWE) and the use of wearables

- Technological changes have enabled us to run studies completely virtually. While there are still limitations for certain research modules (e.g. Telemedicine and Remote Source Data Verification), and while the set-up and preparation of fully virtual studies can be quite time consuming, these changes are opening the door to for more studies run virtually. Such studies bring us closer to the consumer and his/her needs, putting his/her product experiences at the center of the scientific work to be done

Looking ahead, I believe we will see more studies done remotely, opening up new ways of recruiting and following-up with subjects. We will use new technologies, such as wearables, more often to capture the impact of our products on consumer behavior, quality of life and daily performance, with real-world evidence becoming a fundamental part of how we as an industry develop products and claims.

Following a new path to claims generation

THE FUNDAMENTALS OF CLAIMS GENERATION

As new ways of generating claims have come on stream over the past decade, one fundamental rule has not changed: Every claim, regardless of type, must be substantiated with robust evidence.

The type, volume and quality of evidence needed is not universal. While some regions of the world have adopted harmonized regulations governing claims substantiation, others have not. Local knowledge is crucial to avoid unpleasant and expensive surprises later in the process of bringing a claim to market.

There are two broad types of claims in consumer health: commercial claims and health/efficacy claims. Depending on the goal of claims development, you can apply "consumer science" or "clinical science" (see Exhibit 4).

ELEVATING CLAIMS WITH REAL-WORLD DATA

In the past, product claims for consumer health products usually derived from the outcome of clinical trials. As regulatory requirements increased over the years RCTs became the standard to demonstrate efficacy and safety of a product. This is the most scientifically rigorous but also the most expensive approach.

However, as most OTC medicines are 'me too' products or varients of the same active compound, consumer health companies looked for new opportunities to differentiate on the market, focusing on the consumer science route to differentiate through marketing claims, utilizing sales data and HCP recommendations.

In order to develop more specific consumer generated claims for their products, over the past few years, companies have started applying advanced RWD research methods, based on specific consumer surveys; gathering new claim information on perceived product effectiveness or preferences to gain a more intimate insight to consumer wants and needs

While RWD has been in play for marketing claims for a number of years now, the consumer health industry – unlike its Rx counterparts – have been slow to augment clinical research with RWD and the real-world evidence (RWE) subsequent evidence it generates for label/ health claims.

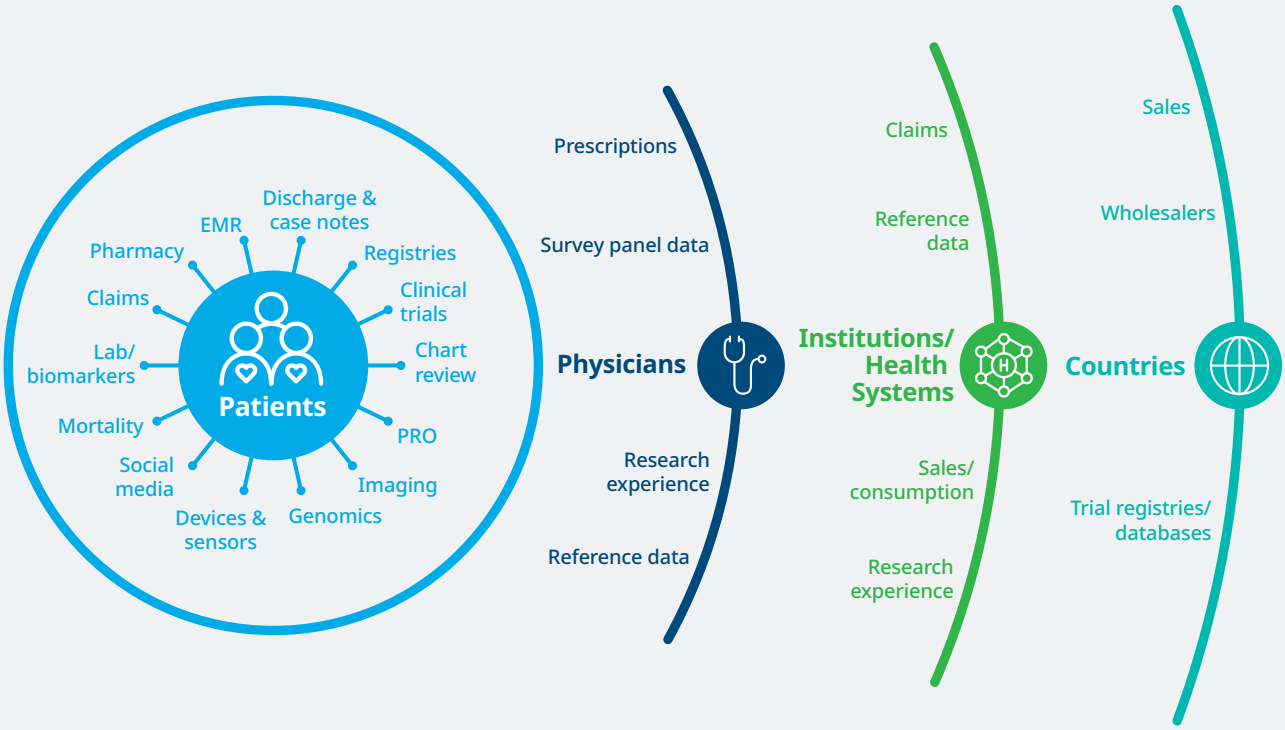
Clinical research remains an important pillar to develop evidence for label claims or to substantiate new indications, and over the past few years we have seen new methodologies come on stream to measure outcomes differently (e.g. digital biomarkers) and complement findings from RCTs to prove efficiency in a real-world context.[5,6]

Exhibit 4: Types of claim and claims substantiation (Source: IQVIA Consumer Health)

Claim Types	Consumer science claims	Clinical science claims
Objective Substantiation	Sales/Market Data e.g. #1 Selling; #1 in Category	Efficacy and safety for new formulations (Typically RCTs)
	Recommendation trackers: e.g. #1 GP prescribed; #1 Pharmacist recommendation	Health related endpoints from scientifically validated wearables and digital biomarkers in a real world context
	Consumer Usage	Label extension and new indications
Subjective Substantiation	Sensory Claims e.g. soothing effect, cooling, etc.	Patient / Consumer Reported Outcomes (PRO tools, VAS)
	Consumer Satisfaction e.g., perceived effectiveness	Effectiveness (when efficacy data is available)
	Preference Surveys e.g., galenic formats	Validated health Questionnaires (e.g. HRQoL, EQ5D)

Claims need to mirror consumer needs

Exhibit 5: Real World Data sources used for pharmaceutical products to create RWE , some of which can be used or generated for consumer health products (Source: IQVIA Consumer Health)



In the context of Consumer Health RWD can be generated through different study designs or analyses, including randomized trials encompassing large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective). The important factor is that RWE provides a better picture on how a product is working in a real-life setting reflecting the actual use in practice without the specific limitation of a RCT. Some of the RWD in Exhibit 5 can provide new avenues for consumer health companies in developing new claim opportunities.

Clinical or real-world research is usually required for products claiming health or disease reduction benefits and such research is highly scrutinized by regulatory authorities. Therefore, it is important to design such trials or RWE approaches very carefully considering all relevant aspects, including consumer relevance and the probability of regulatory acceptance.

But underpinning the application of any of these methods should be a focus on consumer need. The more you approach science in a consumer-centric way, the more you can be assured that you are doing the right things.

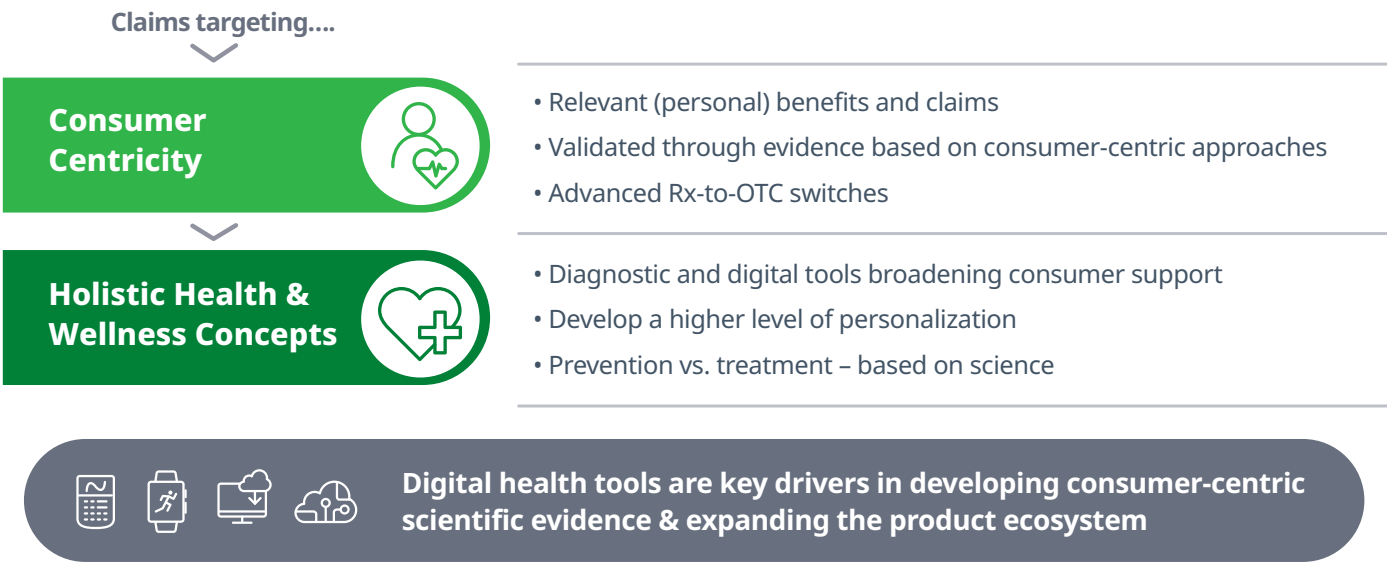
UNCOVERING THE SECRETS TO CONSUMER TRUST

Getting closer to consumers and better understanding what they want from their healthcare products has long been the 'holy grail'. Now with the advent of 'always on' and 'connected' consumers, that goal is within reach.

However, there remains a challenge of ensuring that the data harvested is useful and provides true consumer insights, especially when seeking answers such as, what do consumers really think about a certain product vs. a competing product? How do they use a product in their daily lives? What are consumers really looking for when buying a product?

The changing nature of consumers is also changing the questions that need to be asked. The product and what it does on a basic level is no longer consumers' sole concern (see Exhibit 6). They want solutions to their specific problems; the product must fit their lifestyles and deliver meaningful benefits. Increasingly consumers want to personalize their experience and are expecting additional diagnostic tools to go with their healthcare products of choice.

Exhibit 6: How to Develop Consumer-centric and Holistic Health and Wellness Concepts (Source: IQVIA Consumer Health)

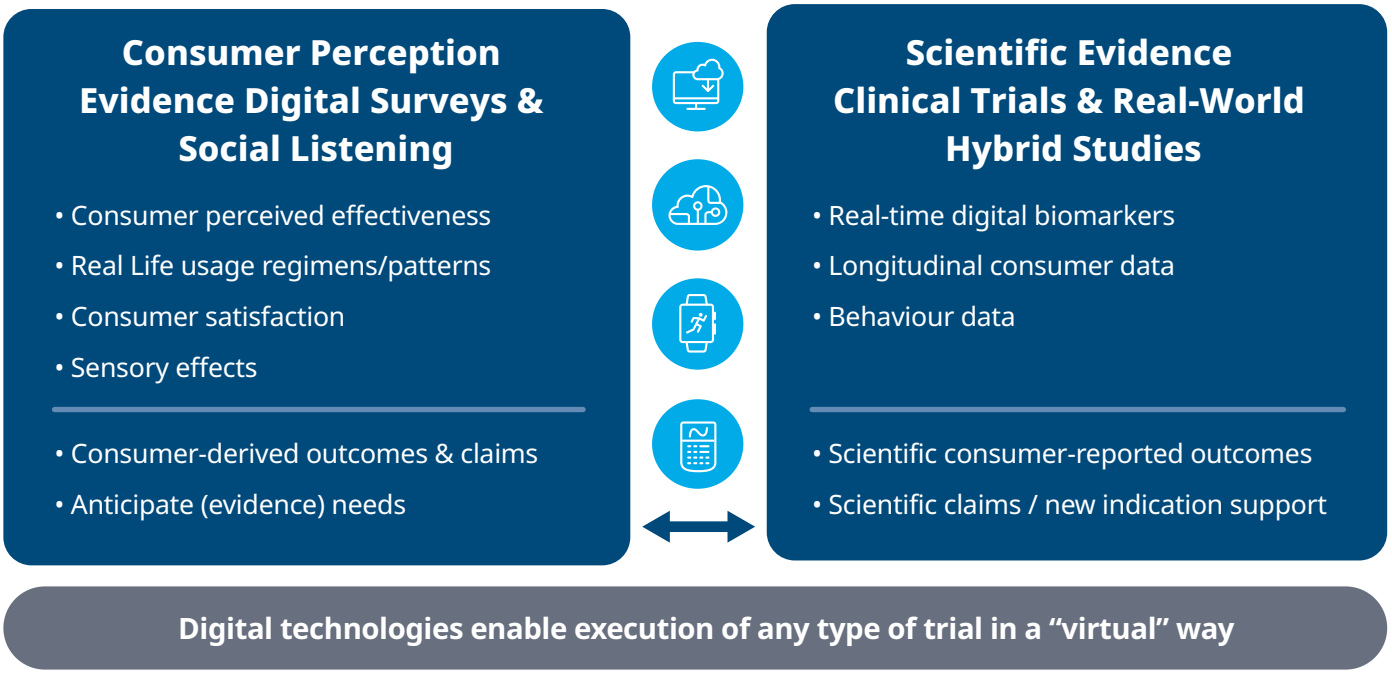


Unearthing these new consumer secrets is one of the keys to increasing value share and applying digital technologies is an efficient way to do this.

New digital-based methods such as social media listening, data mining, RWE, and digital health data deriving from wearables and smartphones can transform the claim substantiation process.

Combining such approaches with artificial intelligence (AI) and machine learning, can now provide faster, more efficient, more accurate and more consumer-relevant insights that add tremendous value to the claims-generation and substantiation process (see Exhibit 7).

Exhibit 7: Advantages of new digital methods to claims development (Source: IQVIA Consumer Health)



Taking social media listening as an example, this research method is providing valuable consumer insights unfiltered by research intervention. Monitoring what is being said online by regular consumers can reveal candid insights in near real-time, which can then be used to identify new consumer needs.

These techniques give a better idea of what consumers want, along with what appeals to them as a claim. Designers of a real-world studies can use this information to incorporate more relevant survey questions, targeting consumer perceived evidence claims in line with expressed needs. This can be used in developing powerful and compelling commercial claims.

In more advanced clinical or real-world hybrid studies (combining elements from clinical study designs with real-world studies) digital biomarkers, observational data and behavior data can all be utilized to achieve consumer-centric outcomes. These outcomes can then be used to develop new label claims and new indications that differentiate from competition or create additional value to a product.

Such approaches represent a significant opportunity for the consumer health industry that has not been sufficiently explored. An added benefit of such studies is that by going digital, many studies can be run virtually, significantly reducing costs.

DIGITAL BIOMARKERS

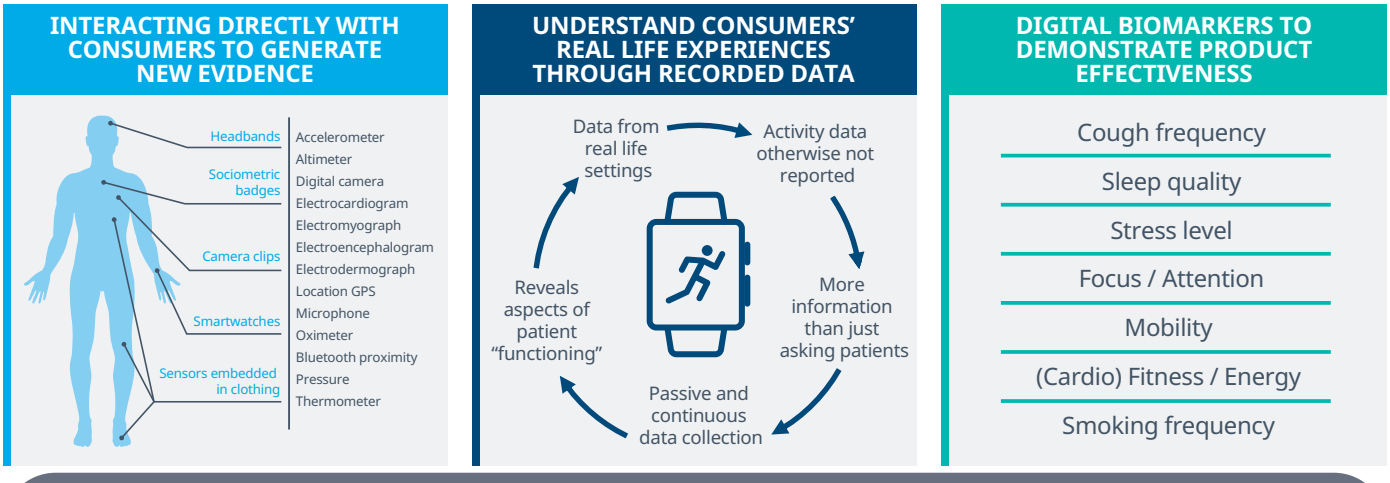
Digital biomarkers are the use of connected sensors, wearables and mobile devices and their capture of biomarker data (any substance, structure, or process of the body, its actions or products) to predict the incidence of disease or health conditions, track aspects of these, or assess the effects and value of treatments or interventions.

HOW TO GATHER REAL-WORLD DATA FOR CLAIMS

Gathering this intimate consumer data has been facilitated over the past few years by the development and use of digital biomarkers derived from different sensors in wearables (smartwatches, fitness bands), smartphones or dedicated devices designed to monitor specific aspects of human activity and function (see Exhibit 8).

As an example, activity monitors can measure movement, rotation and position. Such raw data can be translated into information on number of steps, arm movements, sleep-related movements and overall physical activity. These can be important digital biomarkers demonstrating the efficiency of a

Exhibit 8: Digital biomarkers derived from wearables and other devices can provide new insights on product effectiveness (Source: IQVIA Consumer Health)



"Digital biomarkers are the use of connected sensors, wearables and mobile devices and their capture of biomarker data to predict the incidence of disease or health conditions, track aspects of these, or assess the effects and value of treatments or interventions"

health product and can provide additional information on top of other outcome assessments. This type of data provides important insight into people's habits or routines which are often misreported through traditional studies.

In the case of smoking cessation, a wearable device can deliver an objective measurement of smoking frequency; it can provide new insights on how a calming product aids sleep quality. Or, if data is needed on treating a cough, the device can measure the evolution of coughing frequency and severity through sound recording paired with AI.

Such digital information also has the advantage of being objective and can be measured passively in a continuous manner which is convenient for study participants who do not have to stick to strict adherence or recording protocols beyond wearing the device.

When applying such tools, it is of course important to ensure the quality and validity of the data. In a hybrid design, consumers should only apply those tools which have been validated - as with any other outcome measure. In the case of RWD studies, there may be a need to explore how digital tools that consumers already own can be integrated into a trial to maintain the real-world aspect of the research.

While there are other practical factors to be explored in more detail, it is clear that these digital endpoints can be used to generate new claims around effectiveness as well as comparative claims that may lead to the discovery of new indications.

APPLYING VIRTUAL REAL-WORLD RESEARCH TO INNOVATION STRATEGIES

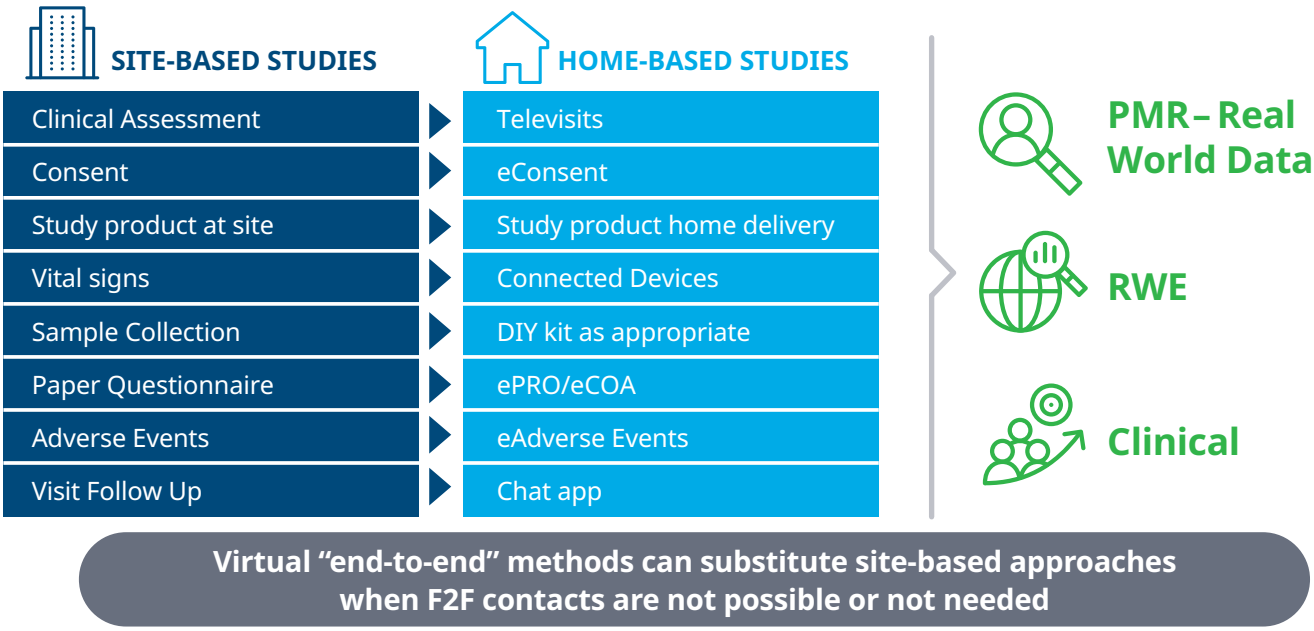
To build new approaches to claims generation into an innovation strategy, a "white space" analysis is necessary to understand consumer / medical needs and insights, as well as a review of the competitive landscape and regulatory requirements.

The strategy will also depend on the type of claims you are targeting: label claims vs. promotion / advertising claims. In all cases, you must apply the most appropriate methodology to ensure the development of claims that:

- Resonate with consumers
- Clearly differentiate the product in the market
- Can be substantiated at a cost in line with the value delivered
- Can pass regulatory or legal scrutiny

Best practice is to have a company-wide claims strategy that crosses product categories and product lines.

Exhibit 9: Virtual Trials Now Mirror All the Elements of Traditional Site-based Studies (Source: ObvioHealth)



Virtual Trials—Simplifying the difficult

Virtual research methods are not new to the consumer healthcare industry. Primary market research has long been conducted utilizing digital methods, allowing for quick, often one-dimensional, insights into consumer experiences and preferences. However, limitations around cost and time have restricted more scientifically robust research in the consumer health space.

Today, virtual elements can mirror components of a clinical study that traditionally have been completed in a costly face-to-face setting (see Exhibit 9).

Direct to consumer elements such as electronic informed consent and electronic questionnaires have been used extensively in the pharmaceutical industry, replacing paper diaries and allowing direct collection of information.

By bringing these technologies into consumer health research, alongside newer technologies allowing for in-home video consultations, enhanced consumer oversight through instant messaging-style chat functions and direct data collection from wearables, researchers can obtain a real-world view of a product's effect with minimal inconvenience to the consumer.

By running studies remotely, rather than at a site, research can be designed to fit seamlessly into the consumers everyday world, allowing an intimate view of exactly how he or she is interacting with a product in a manner which does not impose inconvenience to their day-to-day lives.

According to Erin Haumann (Managing Director APAC, ObvioHealth), "Participation in clinical studies where consumers are asked to attend a face to face clinic visit can become laborious for the consumer. Navigating the commute, wait times, physical assessments and impact on day to day work and life commitments can easily become time consuming for consumers and this can negatively affect retention in the studies and the robustness of the data collected. Because of the near seamless fit with the consumers lifestyle, a virtual study allows for a far greater level of engagement with participating consumers."

"Because of the near seamless fit with the consumers lifestyle, a virtual study allows for a far greater level of engagement with participating consumers."

— Erin Haumann, Managing Director APAC, ObvioHealth

Building a virtual trials platform

When designing a virtual trial platform, several items should be considered.

First and foremost, it is imperative that the platform ensures consumers' privacy and that participants' legal rights are maintained. Compliance with local and international laws around health research and data privacy should be confirmed before engaging with any technology providers.

Flexibility is also crucial. A commitment to virtual real-world research should ideally be portfolio or company-wide and therefore include a platform that can be adapted to support product claims and innovation which may vary widely in nature. A flexible platform consisting of individual modules will allow for deployment across different study designs, enabling an efficient and robust claims process. Similarly, different types and brands of digital health may require multiple forms of consumer data collection and aggregation. Data from wearables, devices, blood draws or imaging should be able to be easily and seamlessly integrated into results.

ENSURING MAXIMUM CONSUMER ENGAGEMENT

The average participant drop-out rate in clinical studies is 30% , which significantly increases the overall cost of research as well as compromising the scientific validity of the eventual result. Ensuring participant engagement with the study is essential to reduce participant loss. To maximise consumer engagement, it is important that the data collection technology be time-efficient and easily integrated into the participant's lifestyle.

The platform should be intuitive in design, with a clean fresh user interface and the ability to custom-build data entry fields as required. Ideally, participants should be able to be presented with a variety of data entry modalities including questionnaires, diary forms, videos, pictures, visual analogue scales, and direct links to wearables to prevent data entry fatigue.

Providing online and offline help such as a library of instructional videos, a 24-hour help desk and the ability to reach out for study assistance via a chat feature will mitigate issues that may result in a negative participant experience.

PLATFORMS DESIGNED WITH CONSUMERS IN MIND

When platforms are designed to be truly consumer-centric and user friendly, participants have a seamless and easy end-to-end experience.

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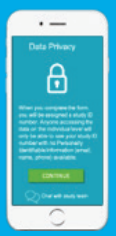
Recruitment

Participants will typically first engage with a virtual research study during the recruitment phase. Increasingly, recruitment is conducted through targeted advertising on social media. Digital recruitment can be exceptionally powerful, reaching the right person at the right time. The ObvioHealth, platform, for example, utilises powerful algorithms combined with digital recruitment methods to reach new pools of potential participants suitable for a specific study more quickly and cost efficiently. Full study recruitment (n=400) was recently completed for a relatively complex target in less than one week.

Prescreening

Once potential participants have expressed interest in a study, there is a need to further screen each participant more thoroughly. Virtual studies can use an online screening process with machine logic that filters out respondents based on answers to questions provided.



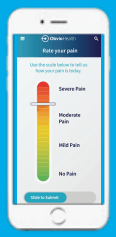
Econsent

Prior to completing any study required procedures, consent of the participants needs to be secured. Depending on the type of research being conducted, consent can range from a simple agreement style checkbox through to full consenting under good clinical practice guidelines with integration of test questions and descriptive videos to explain participant requirements with collection of electronic signatures to document consent. Consideration also need to be given to local language; the virtual trial platform should be able to cater to multiple languages within the study.

Enrollment

When the responses provided indicate eligibility, the participant can download an app designed for the trial and then be guided through the process of creating a user account. Account creation should be very simple and follow a similar format as required for other platforms the consumer will likely be familiar with (such as facebook etcetera).

During the account creating process, It is important to ensure that the participants are who they say they are. The latest technology has multiple methods for identification verification – all compliant with privacy legislation. These range from submission of a selfie with photo identification documentation to utilisation of an in-built device fingerprint and/or face recognition verification through to data linkage with credit or governmental agencies.



Questionnaire

Once consent has been obtained, the participants can be guided through the procedures required by the study. This may include provision of educational and instructional materials to help create linkages between the study database and the participant's wearables, shipping of products, and any data entry requirements. Daily tasks may include survey responses, reminders to use product or submit photos. These can be presented as task reminders within the system, where participants are notified of pending activities through a notification function.

Case study 1: PMR studies

A client seeking to enhance a current product claim was exploring the possibility of changing their product use from treatment to prevention. A virtual trial allowed them to conduct a quantitative survey targeting the specific study population, with stratification to allow data collection from groups of participants who were using the product to treat the condition and then compare this to data collected from groups who were using the product preventatively.

OUTCOME: The study was conducted 100% virtually, completed very quickly and delivered a strong differentiated claim.

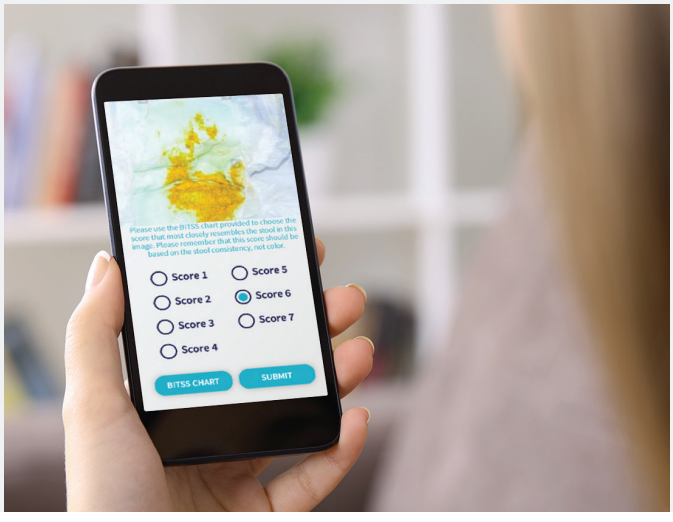
Case study 2: Clinical trials

Given their time and logistical constraints, busy mothers of newborns are a particularly ripe target for virtual studies. In a recent trial, multimedia functions facilitated the uploading of videos and pictures to allow central assessment of stool consistency and changes.

Randomized trials for purposes of product testing can be logistically challenging. A study conducted across the United States to support innovation initiatives called for four different potential product reformulations to be tested. This longer study required multiple data collection points to assess effect on GI health, analysis of stool samples and self-scoring against a global scale. In the past, studies such as this have been site-based. However, this siteless study managed product shipment, AE collection, and relatively intense consumer involvement 100% virtually.

Using targeted social media algorithms and dynamic advertisements to recruit the sample, the virtual platform funnelled potential participants through a series of pre-screening tasks.

OUTCOME: The study enrolled 400 eligible patients in 24 days and was completed end to end in just over a month, a very rapid turnaround for such an intense RCT. In addition to the clinical data obtained, the team was able to integrate more traditional market research elements such as intent to purchase, allowing the sponsor to capture both efficacy and preference claims quickly and efficiently. This time saving translated to faster time to market.



Conclusion

KEY BENEFITS OF VIRTUAL TRIALS FOR CLAIMS DEVELOPMENT

Today's crowded and highly competitive consumer health market makes meaningful product differentiation a challenge. Compelling claims, supported by scientific evidence, are vital to keep products and brands relevant in the minds of consumers, pharmacists and other healthcare professionals.

In this whitepaper, we have seen how technology can enhance the quality, speed and relevance of data collection in order to generate a level of evidence all stakeholders can accept.

The pharmaceutical industry is already embracing these methods. It is time for the consumer health industry to think differently about claim development and embrace the new opportunities we have through digital trials.

There are 3 key benefits in using virtual trials for claim development (see Exhibit 10). Firstly, consumers will feel more engaged in the research and be more likely to adhere to study parameters and less likely to drop out when they feel at home.

Secondly, remote studies can help companies to innovate in the ways they collect evidence, with digital health tools enabling capture of new endpoints and opening up new avenues for claims developments.

Finally, virtual research simplifies execution, reducing the time for recruitment and enrollment 3-to-4-fold with costs that are up to 50% lower, while also reducing data transfer and translation errors.

Exhibit 10: Key benefits of utilizing virtual real-world research to generate claims (Source: IQVIA Consumer Health)

Engage with consumers

- Accelerated recruitment of untapped pools of participants
- Consumer insights captured in near real-time
- Outcome measured where consumers feel at home
- Improved adherence and retention

Innovate & enhance product value

- Larger affordable sample sizes to better substantiate claims
- Consumer relevant / reported endpoints
- New type of endpoints via enhanced digital health tools

Execute with more efficiency

- Faster enrolment (3-4x)
- Lower costs (20-50%)
- Early problem detection
- Paperless / increased data quality

Virtual Real World Research = "The new normal"?... Very - likely "YES"

Exhibit 11: How Virtual Real-World Research Builds Value for the Consumer Health Industry (Source: IQVIA Consumer Health)

Adding value to consumer health businesses

By making virtual real-world research the 'new normal' for consumer health claims generation, the industry can also generate added value for their businesses (see Exhibit 11).

Virtual trials will enable the industry to stay up to speed with the new generation of consumers, exploiting the technology available to get closer than ever before and creating claims that match their diverse and evolving needs.

Put simply, virtual trial technologies make the claim development process more consumer-centric and more in line with the expectations of modern consumers. It is time for the consumer health industry to re-think established approaches and get more creative in making use of available technologies to achieve the next level of product communication in sync with consumer needs.

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Volker has over 28 years of R&D/Innovation experience in the consumer health, natural ingredients industry and academia. After his career start as a university professor in the area of pharmaceutical chemistry he continued in different leading roles in R&D, innovation, licensing / M&A and scientific marketing at Roche, DSM Nutritional Products, Bayer Consumer Health and analyze & realize / Zaluvida.

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