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STAY IN CONTROL  
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**HERO**Framework™  
HEALTH ECOSYSTEM AND REAL-WORLD OUTCOMES

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## THE REGULATORY AND COMPLIANCE LANDSCAPE OF PATIENT CENTRIC RESEARCH

BY DR. JESSICA SANTOS  
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KANTAR HEALTH AIMS TO MINIMIZE POTENTIAL RISKS FOR PATIENTS, STAKEHOLDERS OR FROM A REGULATORY PERSPECTIVE.

Under no circumstances will we compromise patients' safety in any study. Patients' risk-benefit balance will be considered in certain scenarios where ethics committee opinion is crucial.

We will work to set up studies in a proper manner, minimizing risk for clients by ensuring that study results can be published and will not be rejected from regulatory submissions.

Regulators evaluate risk from a wider societal and health economics perspective in addition to patient perspective. For example, they may withdraw a product because of a safety concern, yet patients may still prefer to take it due to few or no alternatives. We will offer you guidance, as enforcement actions will be stricter on high risk studies, but prior IRB/EC approval and relevant regulatory notification will be sufficient for low risk studies.

In this paper, all levels of risks are considered.

WE OFFER A WEALTH OF EXPERIENCE FOR GATHERING AND ANALYZING PATIENT INSIGHTS EFFECTIVELY AND IN ADHERENCE TO REGULATORY AND COMPLIANCE REQUIREMENTS.

As the healthcare industry increases its focus on patient centricity, healthcare researchers find themselves gathering insights on and from patients through a variety of channels, including healthcare providers, biometric data, social media and electronic health records (EHR) data, as well as more intimate insights from patients themselves.

Kantar Health, a leading global healthcare consulting and market research firm, offers a wealth of experience and tools for gathering and analyzing patient insights effectively and in adherence to regulatory and compliance requirements. When clients approach us to conduct a patient study, which on the surface can be vague with unknown risk, we navigate them through the process by defining the study type and identifying the level of risk, while instilling confidence that they've selected a highly skilled research partner for their journey.

For example, a patient study request can go in multiple directions in terms of regulatory, ethics, compliance, privacy and type of study, including Market Intelligence (MI), Real World Research (RWR), Non-Interventional Study (NIS), Health Economics and Outcomes Research (HEOR), or even clinical trials. Key factors and decisions can influence cost, the time line, correct conduct and the final output of the study.

Common patient study objectives can be on an investigational product to gain a general understanding of a disease, such as unmet needs of patients or healthcare providers, to patient preference, to patient adherence or compliance.

In order for you to make the best decisions regarding potential regulatory and compliance issues surrounding your patient centric research, we suggest you review those key considerations outlined in the pages that follow.

KANTAR HEALTH'S HERO FRAMEWORK™ PROVIDES DEEP PATIENT INSIGHT THAT IMPROVES REAL WORLD OUTCOMES.

The HERO Framework™ combines the company's ability to:

- + Listen to the healthcare consumer, where it learns about their health experience and gets to know their thoughts, emotions and wishes for better health.
- + Apply its unmatched healthcare consumer-based evidence, where the company contextualizes any new findings using more than 50 years of observational healthcare studies containing crucial evidence about patient behaviors.

- + Leverage its vast heritage and expertise to create an action-ready blueprint for achieving commercial success.

By getting to the core of the healthcare consumer and the stakeholder's experience, as well as their interactions within the healthcare ecosystem, Kantar Health is the one company that truly understands all of the drivers of health outcomes and translates them into actionable insights for clients.

## 1. KEY CONSIDERATIONS



## WILL THE STUDY RESULTS BE USED FOR REGULATORY BODIES, SCIENTIFIC PUBLICATION, OR INTERNAL BUSINESS INTELLIGENCE?

### PURPOSE

The first question is how the study results will be used. For example, will it be used to satisfy regulatory bodies, such as the U.S. Food and Drug Administration (FDA<sup>1</sup>) or the European Medicines Agency (EMA<sup>2</sup>), or used as part of the submission dossier, released externally in a scientific publication, produced for internal business use only to drive a better understanding of the investigational product's performance, or to evaluate a patient support program.

If the study will be used as part of the dossier for regulatory submission or for publication, then there might be certain criteria that will need to be met in order to satisfy regulatory requirements, such as protocol development, Institutional Review Board (IRB) (U.S. term) approval, or Clinical Research Ethics Committee (EC) (EU term) approval.

### TYPE OF STUDY

The next question is what type of study will it be, e.g. MI, clinical trials, RWR, NIS, or HEOR. Start from the objectives and purpose to determine whether you need an opinion-based study or one that's grounded in real world evidence.

Recently a sponsor's market research department contacted one of our consultancy teams to conduct a marketing research study. However, in further discussions, we found that the study required a RWR approach, which saved them a great deal of potential regulatory risk. On the other hand, we received a request from a sponsor's HEOR department for a RWR study, but again, with further discussions, we determined that the study could be run as a traditional market research study,

which saved a great deal of time and money. Therefore, study type is not always dependent on a client's internal department initiating a study.

When it comes to defining study types, especially in the growing area of RWR, we have standard operating procedures (SOPs) to assist us in study type classification and the assigning of corresponding quality standards and procedures. These SOPs consider study type and research area, are in accordance with international and local regulations, and are based on ethical principles and published quality standards, including: Market Research Guidance (MRG<sup>3</sup>), International Organization for Standardization (ISO<sup>4</sup> 20252, 26362, 9001, 27001) Good Epidemiological Practice (GEP<sup>5</sup>), Good Pharmacoepidemiological Practice (GPP<sup>6</sup>), and Good Clinical Practice (GCP<sup>7</sup>), as defined by the International Conference on Harmonization (ICH).

At Kantar Health, our highly skilled consultant teams rely on support from our global and local compliance departments to determine the operational study type based on the scientific and regulatory aspects of the study design and other sources, including study protocol/outline and questions and answers submitted with the Request for Proposal (RFP). Kantar Health uses the following primary factors to determine operational study types:

- + Data – Individual subject (or participant) health data vs. opinion or aggregated data.
- + Intervention – Interventional vs. observational (non-interventional).

## QUALITY STANDARDS AND GUIDELINES NEED TO BE REFERENCED AFTER STUDY TYPE IS DECIDED.

- + Output of the study – Product clinical effectiveness and/or safety, brand management, monitoring patient preference, adherence and compliance, and disease management, for example.
- + Sites – Site-based vs. subject-based data collection approach.
- + Product focused vs. disease focused – if it's product focused we consider product efficacy and safety; if it's disease focused we consider general unmet needs, adherence or preference, for example.

In addition, we consider secondary factors such as:

- + Sample – cohort retrospective vs. prospective and cross-sectional vs. case control.
- + Purpose – regulatory (registration/ risk management) vs. access (Health Technology Assessment (HTA<sup>8</sup>)/payer) and brand positioning vs. marketing.

The regulatory requirements tend to be stricter, and clearer, regarding product efficacy and safety, and some direct patient interviews can be a grey zone.

Once we've understood all of the aforementioned points, we then decide how the project will be operationally categorized by assigning an operational research area. This can be Market Research (MR), Clinical Research (CR), Health Research (HR), or Pharmacoepidemiology (PE), depending on study type and purpose.

## COMPLIANCE & QUALITY STANDARDS

Once a study type is confirmed, you'll need to determine the correct conduct of the study. This includes the quality standards to follow and industry codes of conduct to observe. For example, if patients are recruited through investigational sites there are specific guidelines to follow that are different from the guidelines that apply to patients recruited from traditional market research panels, although we may ask the same questions.

Our consultant teams will be applying standards specific for the four key operational research areas: MR, HR, PE and CR, for example ISO, GEP, GPP and GCP. Then quality procedures, SOPs, will follow accordingly. When assigning quality standards, we'll determine whether a study is to be performed under MRG (for operational MR studies), as an ICH-GCP<sup>9</sup> compliant study (for clinical trials on medicinal products), as a study performed according to GEP (for HR studies), or one that's GPP compliant (for PE studies).

It's important to note that many countries have specific legislations and guidelines on research involving patients. While this is not a complete list, some notable ones are:

- + Data protection legislations, such as Health Insurance Portability and Accountability Act (HIPAA<sup>10</sup>) in the United States, General Data Protection Regulation (GDPR) in the EU, Personal Information Protection and Electronic Documents Act (PIPEDA) in Canada, and Act on the Protection of Personal Information (APPI) in Japan, for example.

IT'S CRITICAL TO HAVE A SOLID UNDERSTANDING OF WHICH QUALITY STANDARDS AND SOPs ARE REQUIRED IN THE COUNTRIES OF INTEREST IN ORDER TO ENSURE FULL COMPLIANCE WITH LEGAL AND ETHICAL REQUIREMENTS.

- + Good Outcomes Research Practice (GORP<sup>11</sup>) standards, such as the International Society for Pharmacoeconomics and Outcomes Research (ISPOR<sup>12</sup>) or standards used in Public Health or Health Services Research, should also be considered.
- + Quality standards for functional project aspects, such as ISO 20252<sup>13</sup>, ISO 26362<sup>14</sup>, data collection, monitoring, data management, analysis, pharmacovigilance, and writing should be assessed as appropriate.
- + Good Pharmacovigilance Practice (GVP<sup>15</sup>) may be relevant for interventional and non-interventional studies evaluating product safety and effectiveness primarily in the research areas of PE and CR. Respective GVP standards will be taken into account as applicable.
- + If a study involves medical device investigation, the Sponsor must confirm its purpose, e.g. MR, HE, PE or CR. For Medical Device/ Diagnostic Research (MDDR) studies, the ISO 14971<sup>16</sup> norm is developing to become a consensus standard. For operational MDDR studies, compliance with ISO 14971 may then be assessed by regulators, including the European Notified Bodies, and should be considered for MDDR projects in addition to the general standards.
- + For Pharmacoepidemiology/Risk Management studies in Europe and beyond, the European Network of Centers for Pharmacoepidemiology (ENCePP<sup>17</sup>) guide on methodological standards in PE is important; while studies aiming for an ENCePP seal, following the ENCePP standards is obligatory.
- + Standards relevant for projects sponsored by the pharmaceutical industry may be applied.

It's critical to have a solid understanding of which quality standards and SOPs are required in the countries of interest in order to ensure full compliance with legal and ethical requirements. Applying different quality standards and SOPs to a study will have a direct consequence on cost, timing, ability to achieve study objectives, and most importantly, the validity of the study.

## 2. IRB/EC APPROVAL



WHETHER OR NOT TO OBTAIN IRB/EC APPROVAL IS AN INCREASINGLY COMMON QUESTION IN HEALTHCARE RESEARCH INVOLVING PATIENTS.

Whether or not to obtain IRB/EC approval is an increasingly common question in healthcare research involving patients. An IRB/EC is a committee that has been formally designated to approve, monitor and review biomedical and behavioral research involving humans.<sup>18</sup>

The purpose of IRB/EC review is to assure that appropriate steps are taken to protect the rights and welfare of humans participating as research subjects. While there are many variances of IRB/EC by country, most IRBs/ECs act in agreement with the Declaration of Helsinki and GCP, as described in ICH Topic E6 Guide<sup>19</sup> for GCP (ICH-GCP).

Regarding what types of studies need an IRB/EC stamp, application criteria from IRBs/ECs do vary by their set up; however, most competent authorities require all studies that involve “human subject research” to seek IRB/EC approval. However, the term “human subject research” has specific interpretations and may be contradictory to some healthcare researchers’ practices on the daily basis. A human subject is a living individual about whom an investigator, whether professional or student, conducting research obtains data through intervention or interaction with the individual or identifiable private information. Based on this definition, an opinion-based study with no intervention that involves only anonymized information will not require IRB/EC approval, although it may be recommended.

Market research associations, such as the European Pharmaceutical Market Research Association (EphMRA)<sup>20</sup>, have a clear position that market research relating to market or patient behavior of the sort that pharmaceutical companies routinely commission, whether involving healthcare professionals, patients, caregivers or members of the public, does not require IRB/EC approval. However, if a market research study is targeted for academic publication, IRB/EC approval will be needed, as the study will contribute to “generalization of knowledge” and is no longer solely aimed for internal business decisions.

### 3. PATIENT PRIVACY



THE HEALTHCARE INDUSTRY HAS NUMEROUS RULES AND REGULATIONS IN PLACE TO PROTECT PATIENTS' PRIVACY AND HEALTHCARE INFORMATION. HEALTHCARE RESEARCHERS MUST UNDERSTAND AND FOLLOW THESE GUIDELINES.

Researchers from both manufacturer and agency sides face many challenges in protecting patients' privacy – the copious amounts of data being collected; the difficulty in keeping patient data absolutely anonymous at all times; the possibility of discovering patient information of which patients themselves are unaware, such as from genomic sequencing; and the industry as a whole working on innovations that will change diagnosis, treatment and monitoring of patients' conditions – thus creating a potential minefield for privacy regulations.

The healthcare industry has numerous rules and regulations in place to protect patients' privacy and healthcare information. For example in Europe, this information is protected by the GDPR, while in the United States patients are covered by HIPAA. In fact, most countries place healthcare information in sensitive or special categories in their legislations. Foremost, healthcare researchers must understand these guidelines and how to protect individuals' privacy. It's critical that healthcare companies partner with research agencies that have steeped knowledge and commitment to protecting individuals' privacy and comply with country legal requirements.

Several of the most critical regulations, and their implications, are highlighted below:

## THE GDPR

Taking effect in May 2018, the GDPR imposes new obligations on organizations that process the personal data of EU residents, including research agencies, pharmaceutical manufacturers and data analytic companies. While research in general enjoys the wider acceptance of the GDPR, research involving healthcare data still needs explicit consent. Healthcare data is in the "special categories of personal data", which reveal "racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited." (Article 9)

Healthcare research, such as interventional clinical trials or NIS, HEOR or RWR, which has EC approval before execution and publication can be classified as scientific research, but the informed consent process is already well-established and treated as an essential steps within, so they are unlikely to remove the consent process or relax its strict guideline, GCP. Most research sponsored or conducted by a public health authority, such as national health services (NHS), can be categorized as public health research.

Questions remain for healthcare market research, business insight research or research sponsored by corporate businesses, such as pharmaceutical companies, whose objectives can be brand measurement, examination of unmet needs, patient preference, product improvements, general satisfaction, marketing optimization, and support business decision making as opposed to advancement, discovery or development of knowledge in the medical field, which is mostly conducted by academic institutions. Industry associations, such as EphMRA and BHBIA, are publishing guidelines on the position of such research in relation to GDPR. In general, most research will eventually aid better healthcare provision to the general population, and it's recommended to use consent and respond to data subjects' rights.

### HIPAA

Originally enacted in 1996, HIPAA principally consists of the Privacy Rule and the Security Rule. It covers protected health information (PHI) that is disclosed by patients to covered entities<sup>21</sup> which include healthcare providers, health plans and health insurance companies, and healthcare clearinghouses, such as billing services. Business associates<sup>22</sup> – defined as any organization or person working in association with or providing services to a covered entity that handles or discloses PHI – and their subcontractors are also now covered. Any research firm that receives PHI from covered entities are considered as business associates. HIPAA violations are not uncommon. Types of violations can include IT breaches in which hackers target healthcare data, accidental disclosure in which PHI is disclosed to a person who is not authorized to access it, and

data not being processed properly.

Data privacy laws in the United States pose one large discrepancy. While healthcare information is protected under HIPAA, that protection falls away when data are self-reported by the patient, such as when a person participates in a market research study or voluntarily shares data online or via social media. Because the United States does not have an overarching privacy law like the EU, practitioners handling self-reported patient data often turn to Federal Trade Commission (FTC) Act section 5<sup>23</sup> as their guideline legislation.

The data collected through electronic medical records (EMR) or through the HIPAA platforms are very powerful. Researchers can use the data in EMRs as long as the data are de-identified. HIPAA very clearly covers 18 identifiers; and as long as all 18 identifiers have been removed from a dataset, it is considered a de-identified dataset and can be used for research purposes. However, even without using the 18 HIPAA identifiers data can still be used to identify people. For example, analysts can use sophisticated algorithms to determine which group of people has a higher risk to increase insurance premiums. While the United States' privacy laws would not protect against this sort of data usage, in Europe, it would be considered a violation of the basic right to privacy.

### OTHER AGENCIES WORKING TO PROTECT PATIENT PRIVACY

In the United States, data privacy is overseen by the FTC. In 2012, the agency released a report setting forth best practices for businesses to follow to protect consumers' privacy and give them better control over the collection

## PATIENT INFORMATION CAN BE OBTAINED FROM VARIOUS SOURCES, INCLUDING HEALTHCARE PROVIDERS, SECONDARY DATABASES, AND INSURANCE PROVIDERS AS WELL AS THE PATIENT.

and use of their personal data. The recommendations include:

- + Privacy by Design (PbD) – Companies should build in consumers’ privacy protections at every stage in developing their products.
- + Simplified Choice for Businesses and Consumers – Companies should give consumers the option to decide what information is shared about them, and with whom.
- + Greater Transparency – Companies should disclose details about their collection and use of consumers’ information, and provide consumers access to the data collected about them.<sup>24</sup>

In Europe, in addition to the GDPR, data privacy is overseen by individual countries’ data protection authorities (DPA). These agencies have a more active role in looking after patient privacy and are independent, public authorities that are responsible for monitoring the application of data protection laws within their territories.

### IMPLICATIONS – HOW THESE RULES AFFECT HEALTHCARE RESEARCHERS

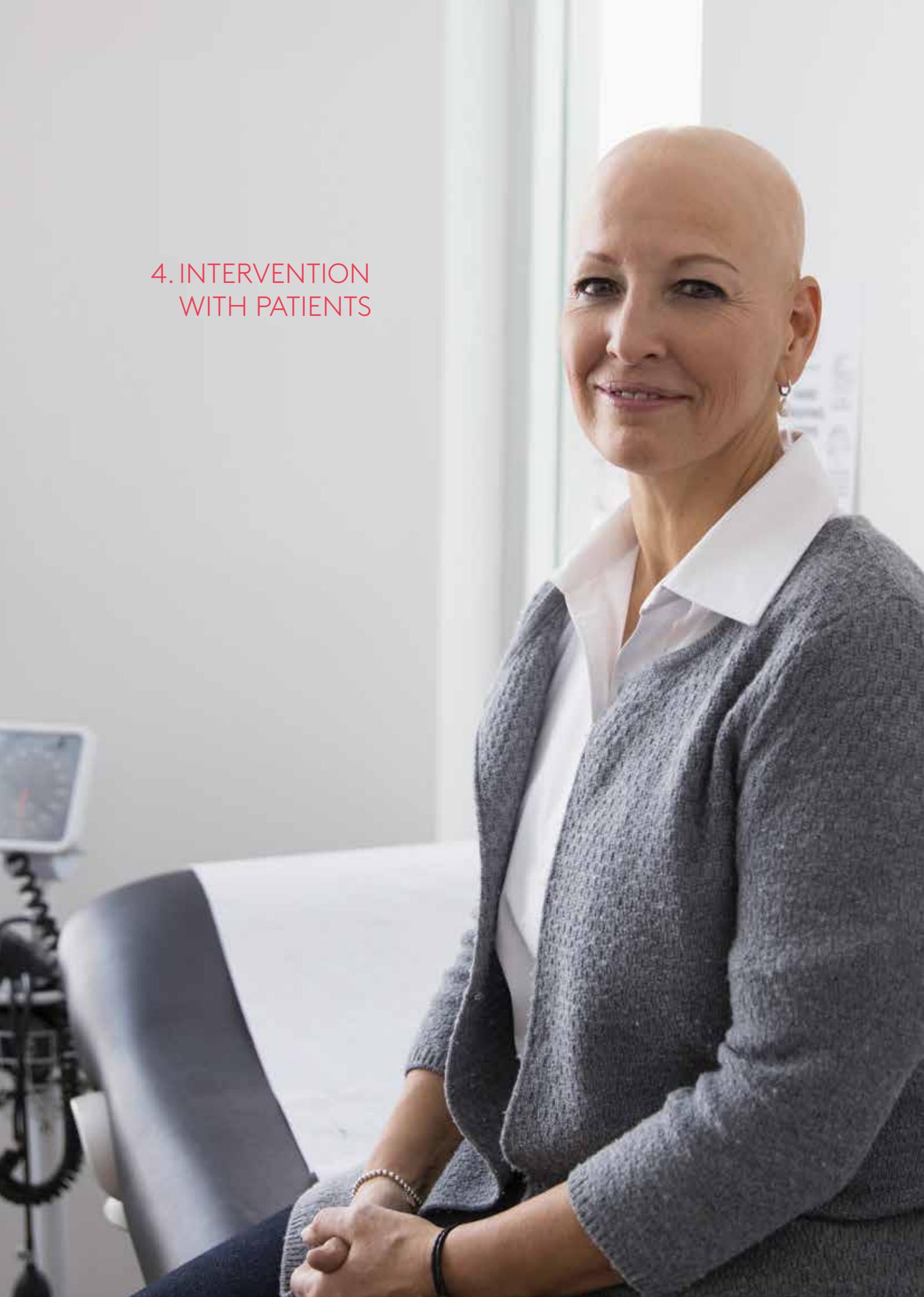
Patient-centric research doesn’t only mean research directly with patients and other healthcare consumers. It also includes asking healthcare providers to release patient information, either via patient records, aggregated data or anecdotal data. The increasing focus on patient privacy has made healthcare practitioners more reluctant to release patient data, and many doctors are confused by what they can and cannot release.

There are several solutions that will reduce the risk of researchers and healthcare providers violating individual patient data and patient privacy laws. One solution is to have the study classified as RWR, as RWR encompasses many types of information, including claims data, clinical trial data, data from EHRs, pharmacy data, and data collected directly from the patient. These data typically conform to privacy regulations because studies that collect real-world evidence are subject to approval and oversight from an IRB or EC.

The second solution is to obtain patient data from a syndicated study. Because these studies have no sponsor, an agency is completely responsible for collecting and analyzing data and ultimately selling aggregated reports, so liability falls to the researchers. Healthcare providers won’t be incentivized from any specific sponsor.

One of the best ways to ensure that a patient’s privacy is not being violated is to receive patient consent by offering them the ability to opt-in or opt-out of having their information shared. However, the GDPR is no longer considering consent as the “waterproof” mechanism for data processing, and the U.S. Department of Health and Human Services encourages healthcare providers and researchers to adequately inform patients of how their data will be used so patients can make a “meaningful” consent choice.<sup>25</sup> In addition to explicit informed consent (signed or not), Privacy Impact Assessment and PbD approaches in the infrastructure are essential to protect patient privacy.

## 4. INTERVENTION WITH PATIENTS



**THE SCOPE OF INTERVENTION IS NOT JUST FOR CLINICAL TRIALS, IT MAY ALSO INCLUDE PRODUCT TESTING OR POTENTIAL BEHAVIORAL CHANGES.**

Research involving intervention with patients have higher risks than observational studies or studies using secondary patient data only.

**CLINICAL TRIALS INTERVENTION**

Clinical trials are essential for the development of medicines. Without them, patients would not gain access to new, and potentially life-saving medicines. EU and international guidelines are in place to ensure that first-in-human clinical trials (Phase I) are conducted as safely as possible. The EMA's existing guideline, released in 2007, provides advice on conducting first-in-human clinical trials, particularly on the data needed for appropriate design and to initiate treatment in trial participants.

The EMA has updated its guideline on first-in-human clinical trials in 2017 . The most important element of the revised guideline will be the enhancement of current strategies to identify and mitigate risks for trial participants and to conduct trials in a safe, efficient and transparent manner to benefit public health.

While the 2007 guideline focused on the single-ascending-dose design used at that time, the practice for conducting first-in-human clinical trials has evolved toward a more integrated approach, with sponsors conducting several steps of clinical development within a single clinical trial protocol (e.g., to assess single and multiple ascending doses, food interactions, or different age groups). The proposed guideline outlines strategies to mitigate and manage risks for trial participants, including principles to be used for the calculation of the starting dose in humans, the subsequent

dose escalation, and the criteria for maximum dose, as well as principles on the conduct of the clinical trial, including the conduct of studies with multiple parts.

Pharmaceutical companies conducting first-in-human trials will soon need to adopt the new guideline in their trial design, execution and monitoring. Trials will not necessarily last longer, but they will require closer monitoring of participants, so costs will rise. Also, RWR practitioners should expect to produce more supporting data and detailed calculations to back up any study design, especially in interventional studies, where the risk to participants is higher. These changes will have far-reaching effects on other aspects of real-world and clinical research, with safety, risk minimization, and better integrated use of data dominating the changes, and these demands extending beyond first-in-human clinical trials, e.g. Phase II-IV.

**PRODUCT TESTING OR HEALTH MONITORING**

In addition to clinical trials, interventions such as product testing or potential behavioral changes with patients are popular subjects among researchers. In Home Usage Testing (IHUT) is a popular consumer testing model to test a product with real consumers before moving forward with a full-fledged product launch. However, the rules change when the consumer becomes a patient, even though it may be the same person. The risks involved for patients and sponsors become much greater or the testing model becomes a clinical trial.

IN SOME COUNTRIES, ANY ADDITIONAL MONITORING THAT IS NOT PRESCRIBED BY THEIR PHYSICIANS AS PART OF THE STANDARD CARE WILL BE CLASSIFIED AS INTERVENTIONAL.

Does wearing a biometric or activity watch or using a phone app that reminds patients to take their medication constitute an intervention? What about a device that requires the patient to indicate when the act is completed? Can we test devices with the drug and needles removed? In some countries, any additional monitoring that is not prescribed by their physicians as part of the standard care will be classified as interventional, such as in France<sup>26</sup>. Yet in some countries, most wearable monitoring devices are classified for general wellbeing, not medical, such as in the United States by the FDA<sup>27</sup>.

Therefore, key factors to consider are whether the product tested is approved by the country's competent authority, whether the product contains active ingredients, whether use of the product is part of a standard care routine, and if the product can cause any potential

harm to patients. If the testing product is not yet approved by each country's competent authority, it's likely that the study will be classified as clinical trials. However, there could be an exception if the prototype is a medical device, e.g. an insulin pen, that is being tested among patients who simply see the concept and no actual usage or interference occurs with standard of care. Additionally, if the testing product is already launched, granted approval by competent authorities and licensed, and prescribed by patients' healthcare providers based on their clinical needs only, the study may be considered a lower-risk study from a regulatory perspective, except in the case of safety surveillance studies.

## 5. FINAL THOUGHTS



KANTAR HEALTH'S HERO FRAMEWORK™ PROVIDES THE MOST HOLISTIC VIEW OF PATIENTS AND THEIR BEHAVIORS AND MOTIVATIONS.

PARTNERING WITH A HIGHLY-SKILLED RESEARCH PARTNER WILL ENABLE YOU TO BETTER NAVIGATE A HIGHLY COMPLEX ENVIRONMENT.

Demand for healthcare research involving patients will continue to increase, especially since the industry is realizing that in order to ensure that prescription drugs, medical devices, and related services and programs truly meet the needs of patients, more information from and on patients is required.

The healthcare industry recognizes that to answer the many key questions at hand it needs comprehensive patient insights. There's great pressure to answer these questions from multiple fronts, including regulatory bodies possessing a "show me the evidence" mentality, pharmaceutical manufacturers constantly seeking to "better understand" target patients, and society in general seeking answers regarding unmet needs and demanding that their voices be heard. As a result, the patient's voice, patient-based evidence and published findings are now placed front and center.

Navigating through compliance issues and many regulatory mazes when designing a patient study is undoubtedly difficult, but success can be more easily achieved through a well-conceived, high-quality-standard approach. Partnering with a highly-skilled research partner will enable you to better navigate a complex environment and give you the confidence that all regulatory and ethical requirements are identified, disclosed, discussed and addressed.

The final words for us, as healthcare researchers, are to always remain focused on the delicate balance of anticipating and managing risks versus benefits, and always do our absolute best to protect the well-being of patients in each and every study design, study execution and reporting of results to our clients.

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## ABOUT THE AUTHOR.



## JESSICA SANTOS, PH.D.

Dr. Jessica Santos is the Global Compliance and Quality Director at Kantar Health, a leading global healthcare consulting and market research firm focused in the life sciences industry. She is primarily responsible for providing oversight and support across Kantar Health's global offices in the areas of regulation, interaction with clients, suppliers and others within Kantar Health, Kantar and WPP. Dr. Santos is responsible for maintaining, anticipating and coordinating all activities with regard to compliance laws/regulations, industry guidelines, pharmacovigilance and client contracts, defining and driving the execution of Kantar Health's Quality Strategy—its approach to measuring and improving quality efforts.

Dr. Santos is an experienced statistician, analyst, methodologist and market research scientist. She gained her reputation through her publications and professional committee work in the industry. She is a frequent speaker and contributor in major conferences and has a Ph.D. in Marketing, an MRS fellowship and Chartered Marketer status.

Dr. Santos is a member of UK Research Ethics Committee, EphMRA, BHBIA and PMRG Government Affairs Committee, reviewer and co-chair of ISPOR, and MRS Professional Development Advisory Board and Examiner.

## TO FIND OUT MORE ABOUT THE HERO FRAMEWORK™

Please visit [www.kantarhealth.com/hero](http://www.kantarhealth.com/hero)

## ABOUT KANTAR HEALTH

Kantar Health is a leading global healthcare consulting firm and trusted advisor to many of the world's leading pharmaceutical, biotech and medical device and diagnostic companies. It combines evidence-based research capabilities with deep scientific, therapeutic and clinical knowledge, commercial development know-how, and brand and marketing expertise to help clients evaluate opportunities, launch products and maintain brand and market leadership. Our advisory services span three areas critical to bringing new medicines and pharmaceutical products to market—commercial development, clinical strategies and marketing effectiveness.