LATE STAGE – SAFETY AND VALUE

inVentiv Health clinical

inVentivHealthclinical.com

» TRANSFORMING PROMISING IDEAS INTO COMMERCIAL REALITY

Table of Contents

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Overview

UNIQUE SOLUTIONS FOR UNIQUE NEEDS

inVentiv Health Clinical Late Stage leaders help world–class companies bridge the gap from development to commercialization. The key is recognizing that Phase IIIb/IV research is undertaken for different reasons than pre –approval studies. Post–approval success is achieved through documentation and persuasive communication of safety and value, and through an operational approach that reflects the unique characteristics of Late Stage: different goals, different measures, different stakeholders, and different time frames.

At inVentiv Health Clinical, we strive to ensure our clients' Late Stage initiatives achieve both scientific and strategic objectives by leveraging our unique perspectives and global resources. The breadth of our experience and services provides us with unique insights into the organizational dynamics that influence a Late Stage initiative, and we are regularly called upon to provide leadership, vision, and training. As a result, our clients achieve consensus and clarity, leading to highly effective research programs that often commence well before product approval. Our clients benefit in achieving both commercial and scientific success through a balanced and operationally cost-efficient approach that recognizes the distinct attributes of the post-approval landscape.

Our services span the spectrum of capabilities to support documentation and demonstration of "real world" safety and value.

SAFETY		VALUE
CLINICAL	**HUMANISTIC**	**ECONOMIC**
• Observational (non-interventional) studies and patient registries • Comparative effectiveness research • Interventional studies • Safety surveillance studies • Risk management/epidemiology • Endpoint studies • Compassionate use programs • Label extension studies	• Patient-reported outcomes research • Quality-of-life instrument development and validation • Quality-of-life studies • Direct-to-patient disease registries	• Cost-effectiveness studies • Economic models • Global value dossier development • Health technology submissions • Meta and database analyses • Pricing and reimbursement support

Global Reach

Services

OBSERVATIONAL RESEARCH AND PATIENT REGISTRIES

Health authorities, insurers, regulators, policymakers, physicians, and patients are all seeking information to better understand "what works" in the real world— in settings that reflect how diseases are treated and how products are utilized without the controls and constraints of traditional clinical trials. Thus, studies must be designed to observe processes and outcomes in actual medical practice settings in ways that don't disrupt the very practices being observed.

An understanding of both the opportunities and the limitations of observational research is crucial to success. That is why we approach observational research by affirming the strategic foundation for a study, since why a non-interventional project is being undertaken impacts how its operational components should be constructed.

inVentiv Health Clinical's experts provide you with valuable insight and perspective and ensure expectations are appropriately set and met throughout the study through pragmatic, scientifically sound design and operational cost–efficiency.

OBSERVATIONAL RESEARCH AND PATIENT REGISTRIES SERVICES INCLUDE:

- Study design
  - *Statistical analysis planning*
  - *Communications planning*
- Overall project management
  - *Management of scientific advisory panels*
- Protocol/guidelines development
  - *Informed consent*
  - *Case report forms*
- Site recruitment and management
  - *Site agreements*
  - *EC/IRB approvals*
- Data management
  - *EDC, EMR*
  - *Paper, hybrid*
- Quality management
  - *Site interaction*
  - *Data quality monitoring and SDV*
  - *Safety reporting*
- Analysis and reporting
  - *Presentations*
  - *Abstracts*
  - *Manuscripts*

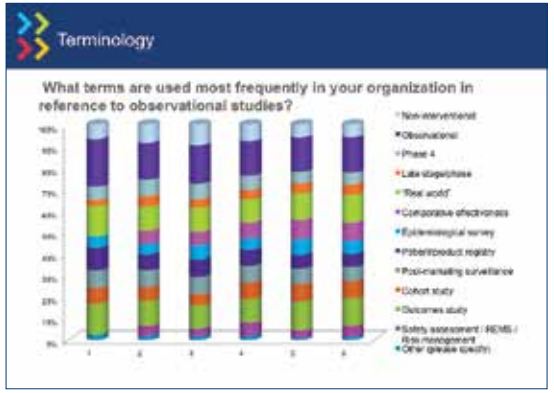
Services

OBSERVATIONAL RESEARCH AND PATIENT REGISTRIES (CONT.)

Emerging Trends in Observational Research

Our widely praised semi-annual Survey on Observational Research provides "below the surface" insights to the industry. By shedding light on both challenges and best practices, inVentiv Health Clinical contributes to improving understanding and consistency in this new and important category of research.

The survey is designed for professionals in a broad spectrum of settings representing a variety of disciplines and perspectives. Respondents number in the thousands, reflecting opinions from industry professionals, regulatory agencies, providers and academicians in more than 40 countries.



Services

INTERVENTIONAL IIIB-IV STUDIES

To transition your product to the commercial setting, you need to consider a variety of research approaches, including additional, traditionally structured, interventional studies to address specific uses and/or populations. These initiatives are often developed within the context of forging new relationships with key providers, opinion leaders, and/or payers.

Interventional studies require both precise and sensitive execution. Because of our broad clinical research resources, we can meet the specific needs of your studies — including design, regulatory support, site recruiting, data management, and statistical analysis.

Expanded Access and Compassionate Use Studies

inVentiv Health Clinical has industry-leading experience in the development and implementation of the specialized initiatives designed to ensure at-need populations can continue to benefit from innovative therapies — even as the products are receiving final regulatory evaluation. By ensuring these studies generate valuable experience data, we can maximize their value while maintaining a focus on overall safety and patient access.

Endpoint Studies

Our endpoint management team includes registered nurses and clinicians who collaborate with you to collect information from sites and manage the flow of the event data to the adjudication committees. The endpoint management team works closely with sites throughout a study to rapidly obtain the critical source documents needed to report potential clinical events immediately. Using state-of-the-art online tracking tools to effectively manage the collection and review of event information, the team collaborates with data management and monitoring teams to ensure that all events are reported and documents are submitted as quickly as possible.

THE ENDPOINT MANAGEMENT TEAM HAS SIGNIFICANT EXPERIENCE IN:

- Developing adjudication charters and guidelines for the endpoint review process
- Conducting endpoint programs requiring adjudication of events in multiple therapeutic areas
- Preparing, disseminating, and tracking outcome packages, including:
  - *Copies of CRFs*
  - *Query responses*
- Supporting source documents for review by clinical events committees

Services

HEALTH ECONOMICS AND OUTCOMES RESEARCH (HEOR)

Generating relevant economic and humanistic evidence for your stakeholders requires a multidisciplinary approach to the design, execution, and analysis of data. Using internal resources and global partners, inVentiv Health Clinical addresses such complicating factors as the differing approach to health care delivery and the cost of health care resources in different countries. inVentiv Health Clinical's HEOR studies and analyses focus on the economic impact of treatments, diseases, and conditions, including the direct costs of medical expenditures and indirect costs, such as those associated with work loss and disability.

INVENTIV HEALTH CLINICAL EXAMINES AND ESTABLISHES PRODUCT VALUE THROUGH A BROAD RANGE OF SERVICES, INCLUDING:

- HEOR portfolio planning
- Comprehensive economics and outcomes literature reviews
- Burden/cost-of-illness studies
- Treatment pattern analyses
- Trial/market-simulation modeling
- Global cost-effectiveness models
- Management of economic endpoints in clinical trials
- Pricing and market access strategies
- Patient-reported outcome (PRO) studies, including quality-of-life and health utility studies
- Retrospective cost-effectiveness and resource utilization studies
- Global and country-specific value dossiers

Services

AN UNPARALLELED CONTINUUM OF SERVICES

Through the inVentiv Health family of companies, inVentiv Health Clinical affords clients research support capabilities in all phases of drug and device development. In many ways, our Late Stage services serve as a critical bridge from pre-approval product development research to post-approval commercialization activity. Moreover, we are uniquely able to present a unified and unparalleled set of services to support client needs in achieving this vital transition. our broad span of convergent services are provided — independently or in a coordinated manner — by these and other members of the inVentiv Health family:

ParagonRx®

Risk management, REMS, and optimal use programs for pharmaceuticals and medical devices designed to mitigate risks and optimize safe product utilization.

Adheris

For more than 19 years, Adheris has been helping patients stay on therapy by offering pertinent educational information to patients taking medication for chronic conditions.

CampbellAlliance®

The leading management consulting firm for biopharmaceutical companies. Practices include Brand Management, Business Development, Clinical Development, Commercial Effectiveness, Pricing/Market Access, and Medical Affairs.

inVentiv THERAPEUTICS INSTITUTE

Effective education of healthcare providers and patients is a key element to achieving desired health outcomes. iTI provides critical support through interactions with degreed health professionals.

inVentiv PATIENT ACCESS SOLUTIONS

Full -service patient access and reimbursement programs that enable patients to achieve optimal therapeutic benefit through continuity of treatment.

Vision

A COMMITMENT TO LEADERSHIP

The Late Stage landscape continues to evolve. As such, today's solutions need to be regularly assessed for ongoing relevance. At inVentiv Health Clinical, we continually challenge ourselves to develop and "operationalize" innovative yet strategically and scientifically sound solutions for our clients. Moreover, we take seriously our responsibility as industry leaders to provide direction, vision, and clarity. And while the Late Stage environment reflects an increasing level of regulatory requirement, we welcome the responsibility of helping our clients transform requirements into opportunities. we believe there is no better or more important setting than Late Stage.

... AND INNOVATION

Our inVentiv Health Clinical Physician's Network is another example of our innovative thinking and understanding of the practical realities of post–approval research. By proactively educating and enlisting the support of thousands of potential "real–world " research participants, we can rapidly start our Late Stage studies with active and committed practitioners.

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