

2020

Latest information on our
clinical advisory services



CLINICAL STRATEGY

Get your product the competitive edge and to
market faster with a robust clinical strategy

KW Advisory

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CLINICAL STRATEGY

Your product's clinical strategy is an overarching master plan that guides the actions to achieve the long term aim of the product. It is driven as well as drives the reimbursement, regulatory and marketing strategies.

The clinical strategy takes the form of a clinical development plan whose key objective is the generation of sufficient clinical evidence.

**“Strategy is a pattern
in a stream of
decisions”
Henry Mintzberg**

Components of the Clinical Development Plan:

Literature review
Individual trial design(s)
Endpoints selection
Investigators selection
Target patient population
Data collection points
Appropriate statistical methods

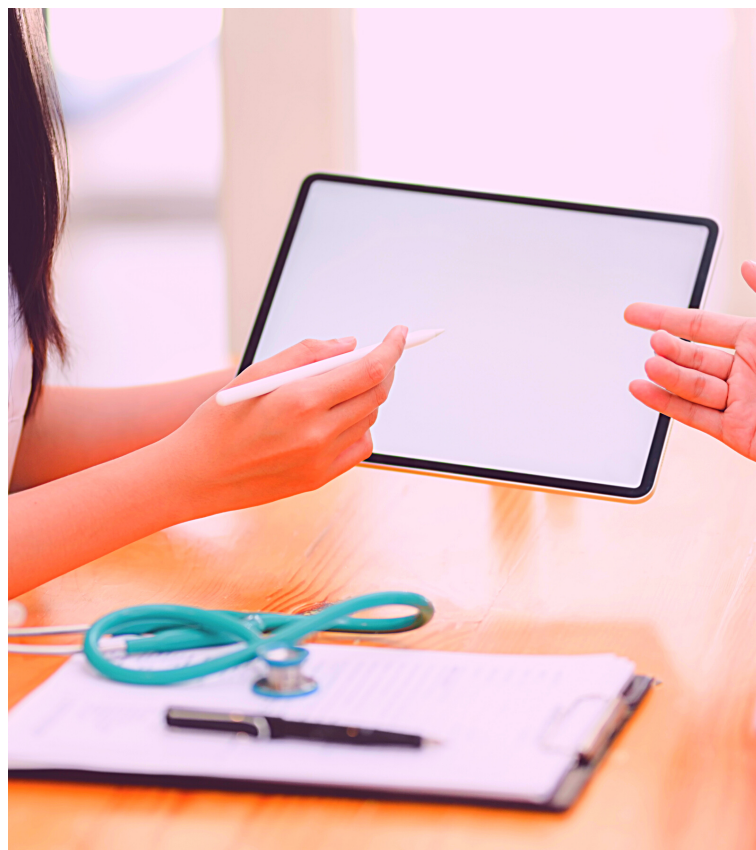


SUCCESS FACTORS

- ✓ Competitive advantage
- ✓ Addresses specific regulatory requirements
- ✓ Provides clinical evidence to justify reimbursement decisions
- ✓ For medical devices it is developed in tandem with the device during the distinct phases of product development as design decisions might influence both risk management and claims

CLINICAL ADVISORY SERVICES

- **Global clinical strategy development** including reimbursement, regulatory and marketing considerations
- **Protocol development** assistance: consultation on study designs, endpoints, and objectives
- **Scientific and medical oversight** of on-going trials
- **Management of key opinion leaders** and scientific advisory board
- **Advisory consultation**
(includes discussions with the relevant team and stakeholders and/or review and inputs into the relevant following documents):
Clinical evaluation report;
Protocol design and development;
Investigator brochure;
Instructions for use;
Case report form;
Informed consent;
Site selection;
Investigator meetings;
Clinical trial agreements



ABOUT US

KW Advisory has extensive experience designing numerous clinical development plans and working with study sponsors to conduct research at sites best able to support the specific pharmaceutical and medical device from entry into clinical development through product launch and real-world evidence generation.

Contact Us:
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to discuss further

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