Curriculum and Course program

CLINICAL EVIDENCE AND HTA IN MEDICAL DEVICES (MD) AND IN VITRO DIAGNOSTICS (IVD)
The road to market access and reimbursement in Europe

A hybrid and virtual educational and training program
by help of
- online lectures
- podcasts,
- virtual break - out sessions,
- group discussions
- virtual “meet the professor” tutorials
- pre-reads
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Learning objectives:

- understand EU regulatory framework for devices and IVDs
- understand the focus on lifecycle management
- learn and recognize the new EU regulation of clinical evidence generation
- understand the principles of evidence - based medicine
- learn about the basic elements of GCP (good clinical practice)
- learn about the concepts of clinical trials
- understand the basic elements of health economy
- get insights into the European challenges in health economy and value generation
- understand the key elements of health outcome value descriptions
- understand HTA and reimbursement processes
- learn about the DRG systematic
- understand all stakeholder’s perspectives in the HTA and reimbursement process
- validate the importance of data selection and description for dossier generation
- evaluate and discuss practical use cases
    - stakeholder mapping for HTA and reimbursement
    - Clinical trial strategy
    - Presentation of clinical evidence
    - HTA dossier generation

THE PROGRAMME IS CREATED FOR MEMBERS OF

- Biotech/Medical Device Industry (medical, marketing, regulatory, market access, product development, general management, etc.)
- Health Insurers
- Health Care Providers / Commissioners
- HTA & Consultancy Agencies
- Educational & Research Institutions
- Health Policy Organizations

Course Language: English

Learning outcomes verification: MCQs and documented group work

Academic valuation: 10 ECTS

Target population: international

Curriculum and Programme

THE REGULATORY PROCESS

Key elements:

- Overview: From MDD to MDR
- CE Marking: technical file or design dossier
- Device class and product families
- Risk management file review
- Clinical evaluation report

CLINICAL EVIDENCE COLLECTION

Key elements:

- Product life cycle planning MDs and IVDs
- Strategy and Labeling,
- The clinical trial process
- The rules of GCP
- The clinical documentation and review process
- Post-market surveillance (process, plan, effectiveness, and results),
- Impact of KOLs (key opinion leaders)

Practical group work/business case: the clinical trial plan

CLASS III & AIMD (*ACTIVE IMPLANTABLE MEDICAL DEVICES)*

Key elements:

- Clinical data requirements,
- Economic considerations
- Value documentation,
- Notified bodies

HEALTH CARE AND HTA & REIMBURSEMENT SYSTEMS

Key elements:

- European Health Care Systems and funding processes,
- The stakeholders and their perspectives
- The finite health care budget - how to escape
- European variety of Reimbursement systems,
- Inpatient & outpatient setting

Group work/business case:

- stakeholder mapping
- HTA/reimbursement process – European differentiation

DOCUMENTING VALUE & FUNDING INNOVATION

Key elements:

- The importance of DRGs
- Innovation budgeting process
- Understanding key markets (e.g. A, D, F, UK)
- Turning clinical evidence data into health economic values
- Defining the needs for specific health-econ studies
- Registries and Real World Data (RWD)
- Establishing the value narrative
- DOs and DONTs in final HTA dossier/narrative creation

BEST PRACTICE IN VALUE DOCUMENTATION

Guided Business cases and group work:
Interventional Cardiology, Orthopedic surgery, ENT

STAKEHOLDERS & THEIR PERSPECTIVES

- The clinician´s perspective
- The payer perspective
- The regulator´s perspective
- The patient´s perspective

DOCUMENTING VALUE

Key elements:

- The device life cycle
- Integration of data generation into the entire process
- Do's and don'ts in data generation

INTERACTIONS WITH STAKEHOLDERS

Key elements:

- Value arguments vs. Stakeholders perspectives
- Principles of successful pricing discussions
    - At hospital level
    - At regional or state level
- Building alliances and win-win situations
- Dos and DONTs in stakeholder`s discussions

SCIENTIFIC COURSE DIRECTORS:

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