Healthcare Technology Engineering

WARWICK

Design, assessment and management

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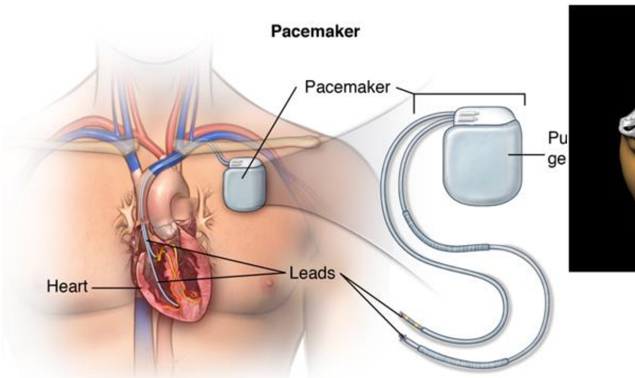
Healthcare technologies

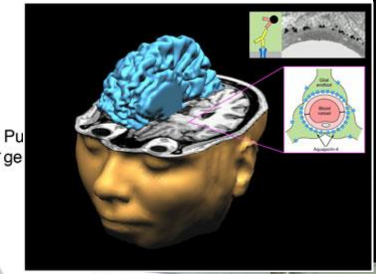
According to WHO definition, healthcare technology refers to any application of organized knowledge and skills in the form of *medicines*, *medical devices*, *vaccines*, *procedures* and *systems* developed to solve a health problem and improve quality of life.

Therefore healthcare technologies include medical devices and medical plants (i.e. surgery theater) which involve directly BMEs

GOALS

Healthcare technologies





Medical Devices

WHO definition:

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Medical Devices

FDA definition

A medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Medical Devices

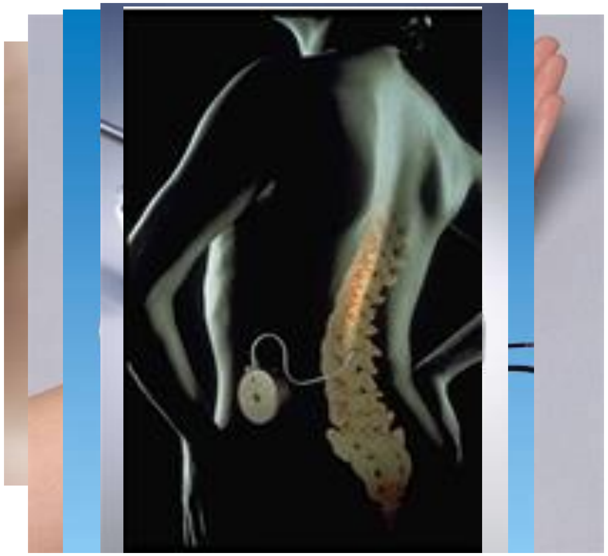
European Commission

A **Medical Device** is defined in Directive (93/42/EEC) as: "Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for the proper application, intended by the manufacturer to be used for human beings for the purpose of :

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted by such means."

According to Directive **2007/47/EC,** which has amended the Directive 93/42/EEC, **Medical Device** means: "any instrument, apparatus, appliance, *software*, material or other article, whether used alone or in combination…"

Medical Devices



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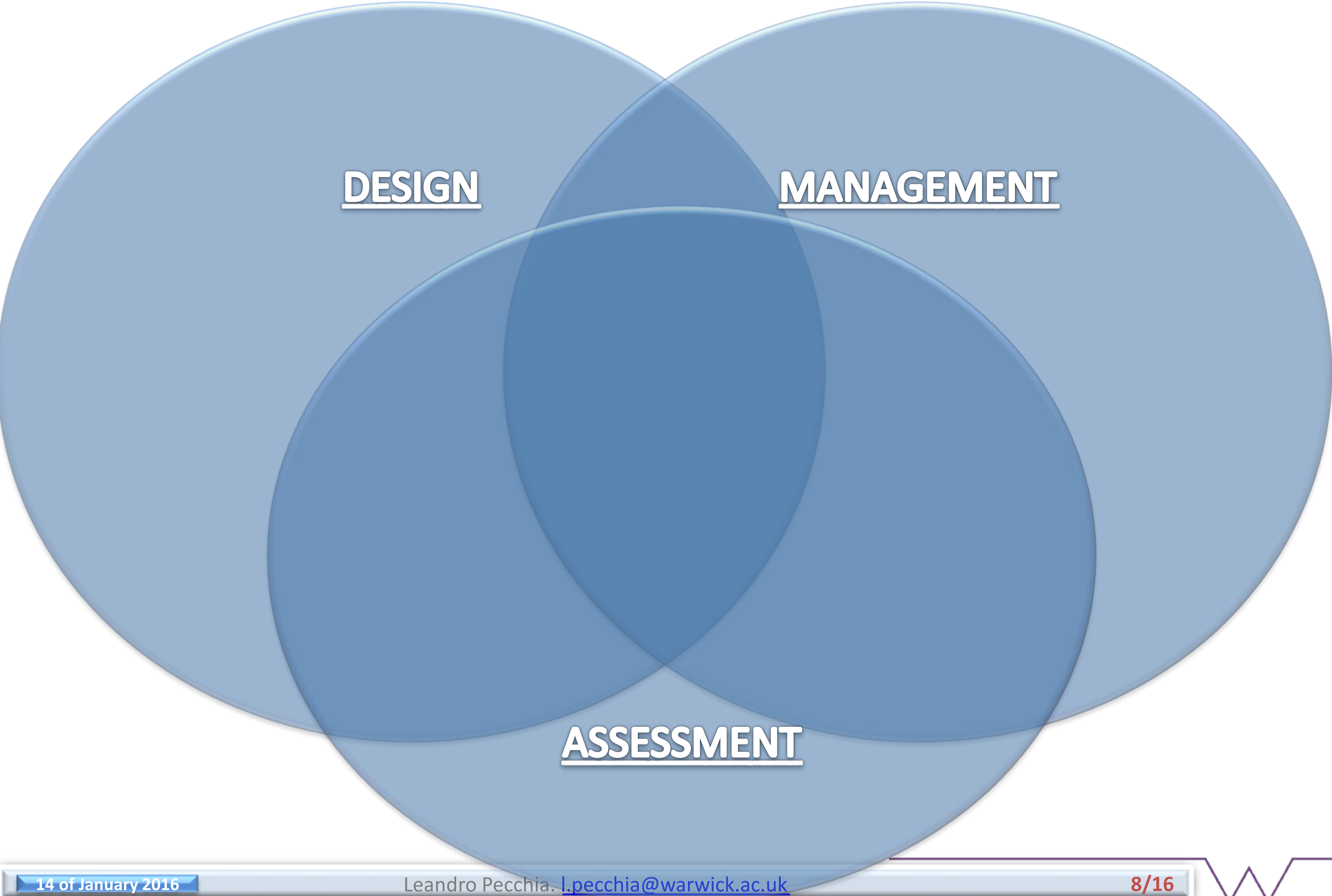
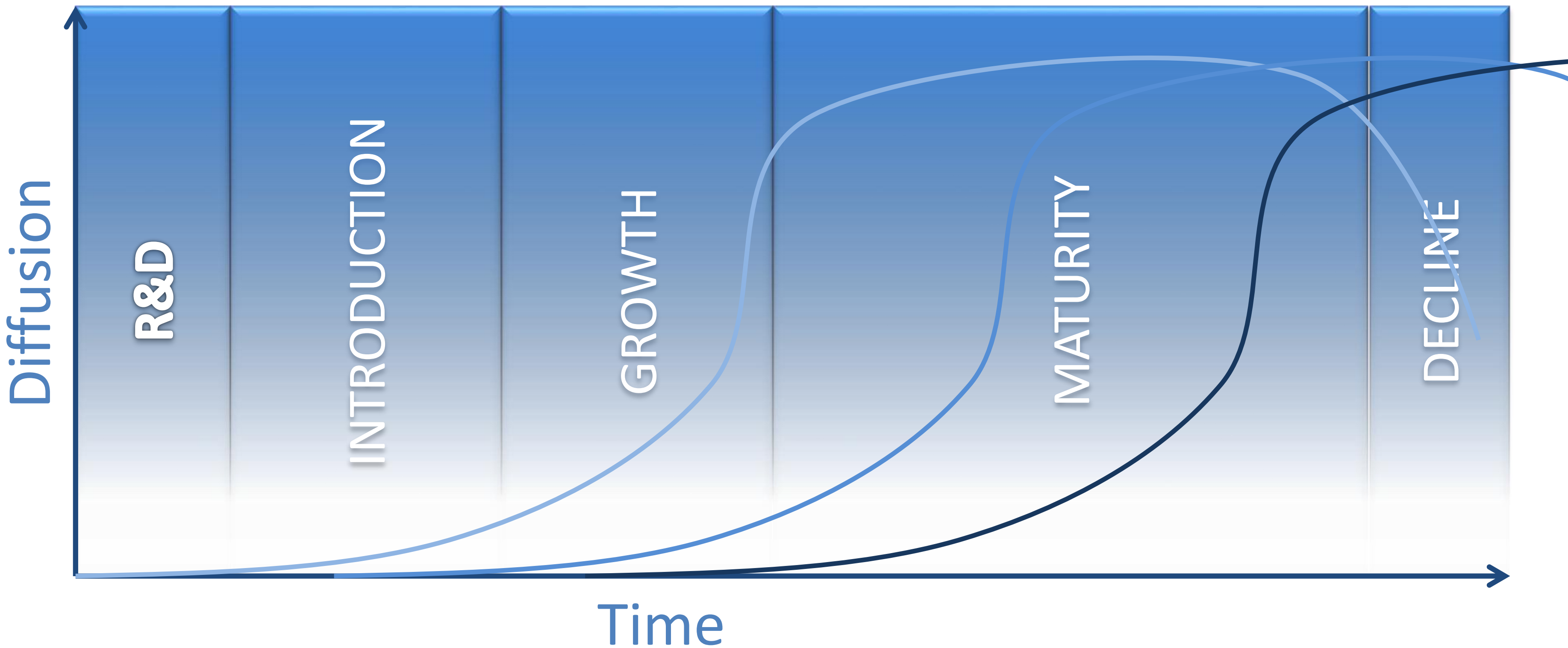
Healthcare technologies

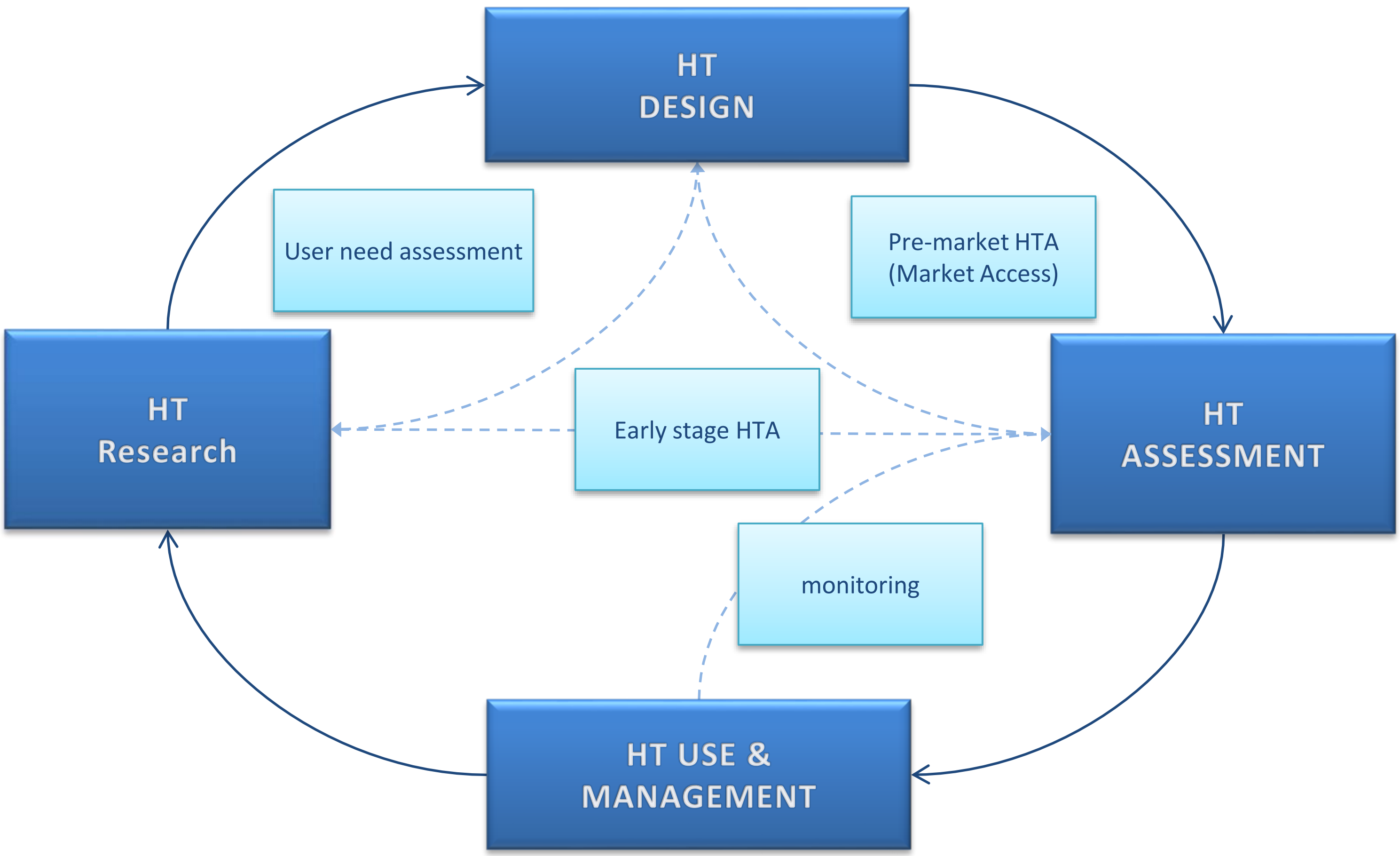


HT life

Healthcare technology life?



HT life cycle



Module organization

1- HEALTH TECHNOLOGY ASSESSMENT

2- HEALTH TECHNOLOGY MANAGEMENT

3- HEALTH TECHNOLOGY DESIGN

…why?

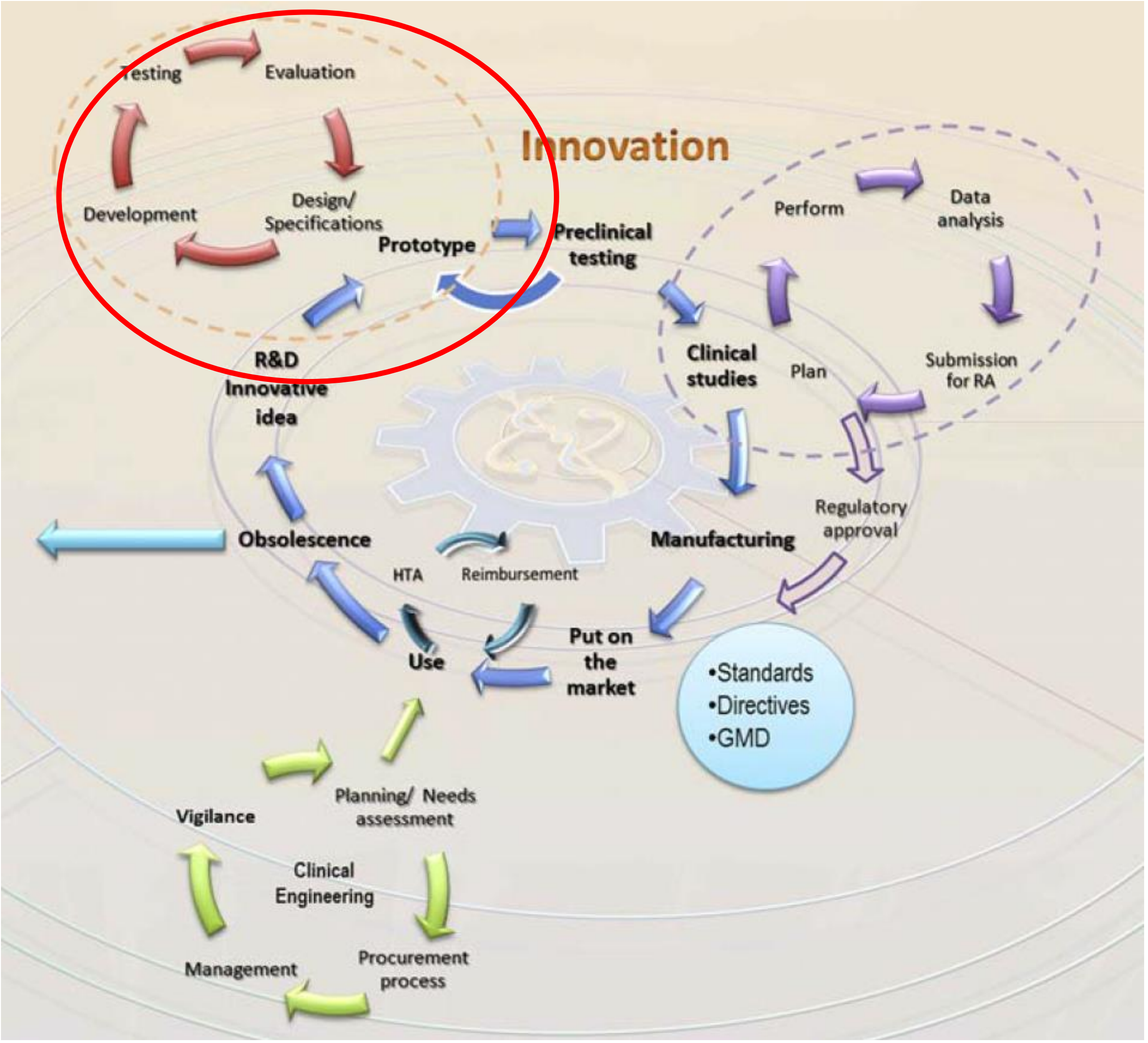
Healthcare technologies

Biomedical Engineering is not simply a subset of modern medicine. Modern medicine predominantly secures important advances through the use of the *products of biomedical engineering** [healthcare technologies]

*European Economic and Social Committee, Official Journal of the European Union, (2015/C 291/07)

BME impact

HT life cycle into the context



*from N. Pallikarakis et al.: http://store.elsevier.com/Clinical-Engineering/Roberto-Miniati/isbn-9780128037676/

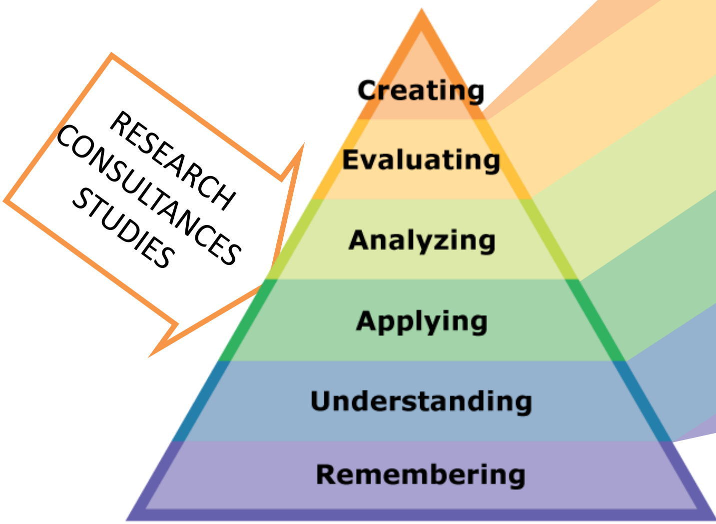
Lectures

Week	Date	Lecture	Date	Lecture
WK1	[09/01]	Intro/PK	[11/01]	eLearning: EBM/MA
WK2	[16/01]	EBM META-ANALYSIS	[18/01]	META-ANALYSIS Lab
WK3	[23/01]	META-ANALYSIS Lab	[25/01]	eLearning
WK4	[30/01]	HTA	[01/02]	HTA
WK5	[06/02]	Clinical Engineering	[08/02]	SEMINAR: HT 4 Falls
WK6	[13/02]	eHTA	[15/02]	eHTA Lab
WK7	[20/02]	Medical Dev Safety	[22/02]	Medical Location
WK8	[27/02]	HT Management	[01/03]	HT design, usability, safety
WK9	[06/03]	Individual presentations	[08/03]	SEMINAR
WK10	[13/03]	HT design cycle	[15/03]	Group project presentations

Assessment

- **Individual Essay (40%):** **[2k words]**
  - Each of you will focus on 1 technology and write a report on it:
    - Physical/medical principles
    - Block diagram and main components
    - Maintenance/acquisition issues
  - Assessment:
    - report [Week 20]
    - presentation [Week 23]
- **Group project (60%):** **[6k words]**
  - Systematic review with meta-analysis on a subject of you choose
  - Assessment:
    - interim report [Week 23]
    - presentation [Week 24]
    - final report [Week 30]

Method



Bloom's Taxonomy

Aim	Method	Assessment
Produce new original work	Individual/group design	Solve a problem
Justify decisions Appraise, argue	Critically review Projects, design	HTA
Draw connections, Associations, dependencies	Divide et rule MCDA	Given a problem, analyse the sol.
Show/discuss practical solutions	Exercises, practical	Analytical problems
Explain Ideas Into context	Group/self reflections	Chose a method
Recall practical facts	Explain, read, repeat, context.	Questionnaires..