

SEE Quality in Pharmacy Summit

Presentation, on October 24, 2015, Belgrade, Serbia

Taking advantage of excellence in science and innovation

Hans H. Linden, EUFEPS

Leaders...

- **Visionary**
- **Strategic**
- **Charismatic**
- **Executive**
- **Managers**
- **Administrative**
- **Effective**
- **Efficient**
- **Inspiring**
- **Team-building**
- **Coaching**
- ...

Leaders...

- Visionary
- Strategic
- Charismatic
- Executive
- Managers
- Administrative
- Effective
- Efficient
- Inspiring
- Team-building
- Coaching
- ...

Leadership Dimensions Roles and Profiles



**Managerial
Leadership**

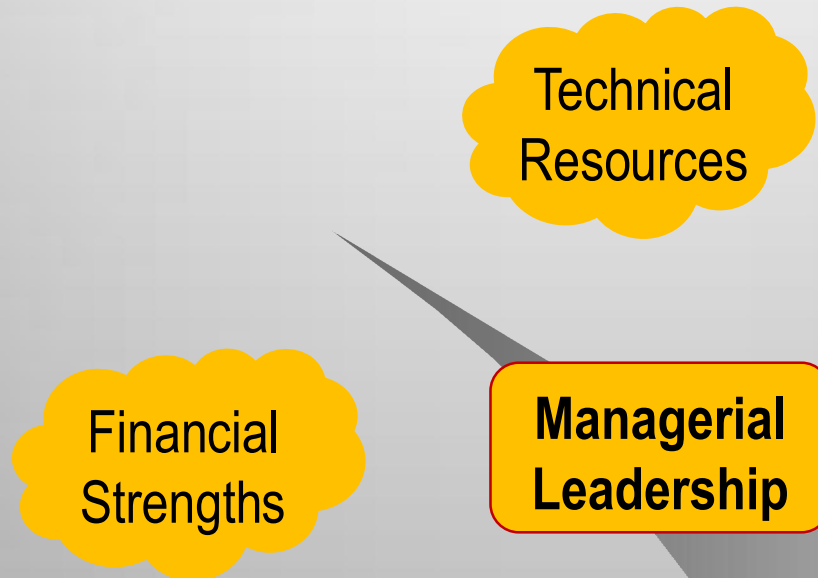
Leadership Dimensions Roles and Profiles

Technical
Resources

**Managerial
Leadership**

But not only...

Leadership Dimensions Roles and Profiles



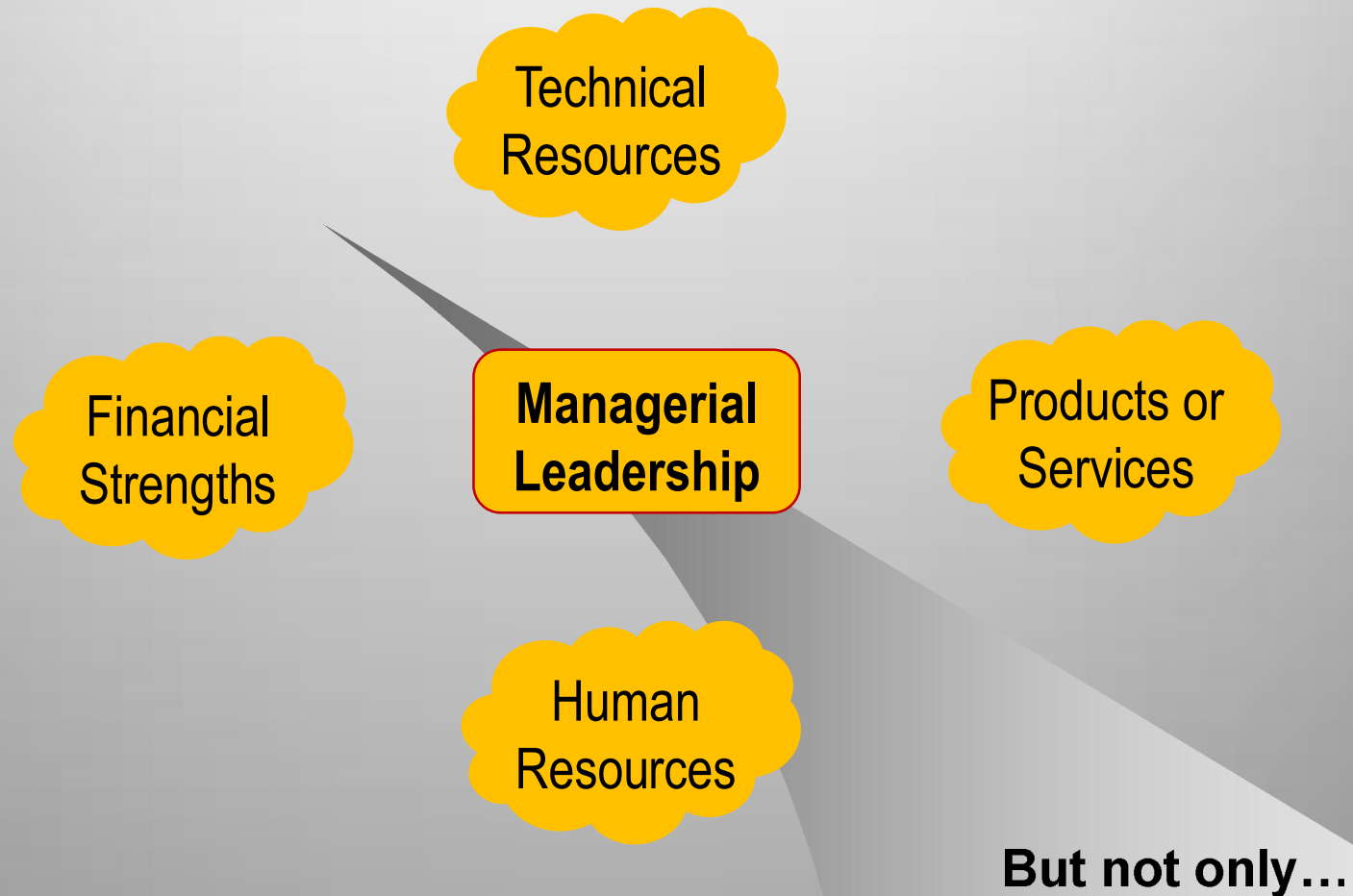
But not only...

Leadership Dimensions Roles and Profiles



But not only...

Leadership Dimensions Roles and Profiles



Leadership Dimensions, Roles and Profiles



**Strategic
Leadership**

Leadership Dimensions, Roles and Profiles

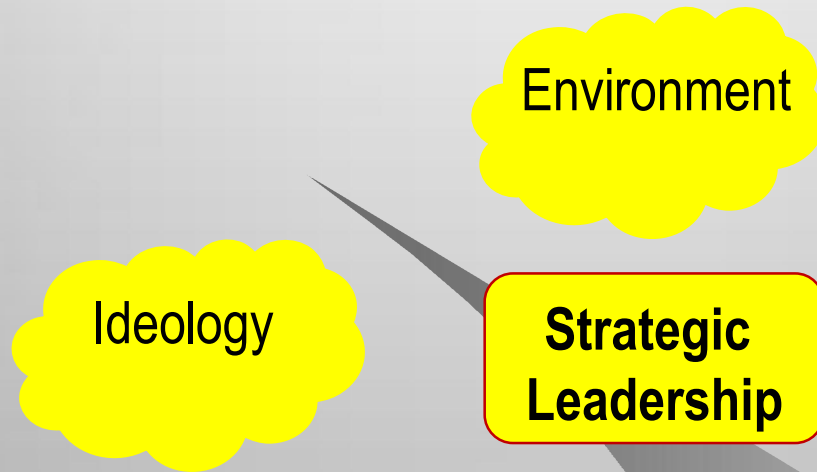


Environment

**Strategic
Leadership**

But not only...

Leadership Dimensions, Roles and Profiles



But not only...

Leadership Dimensions, Roles and Profiles



But not only...

Leadership Dimensions, Roles and Profiles



But not only...

Leadership Dimensions, Roles and Profiles



**Coaching
Leadership**

Leadership Dimensions, Roles and Profiles

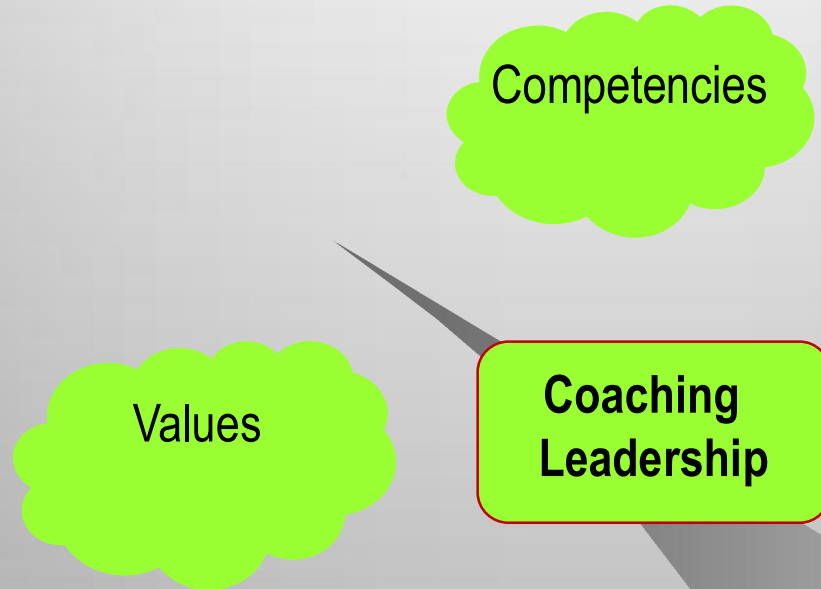


Competencies

Coaching
Leadership

But not only...

Leadership Dimensions, Roles and Profiles



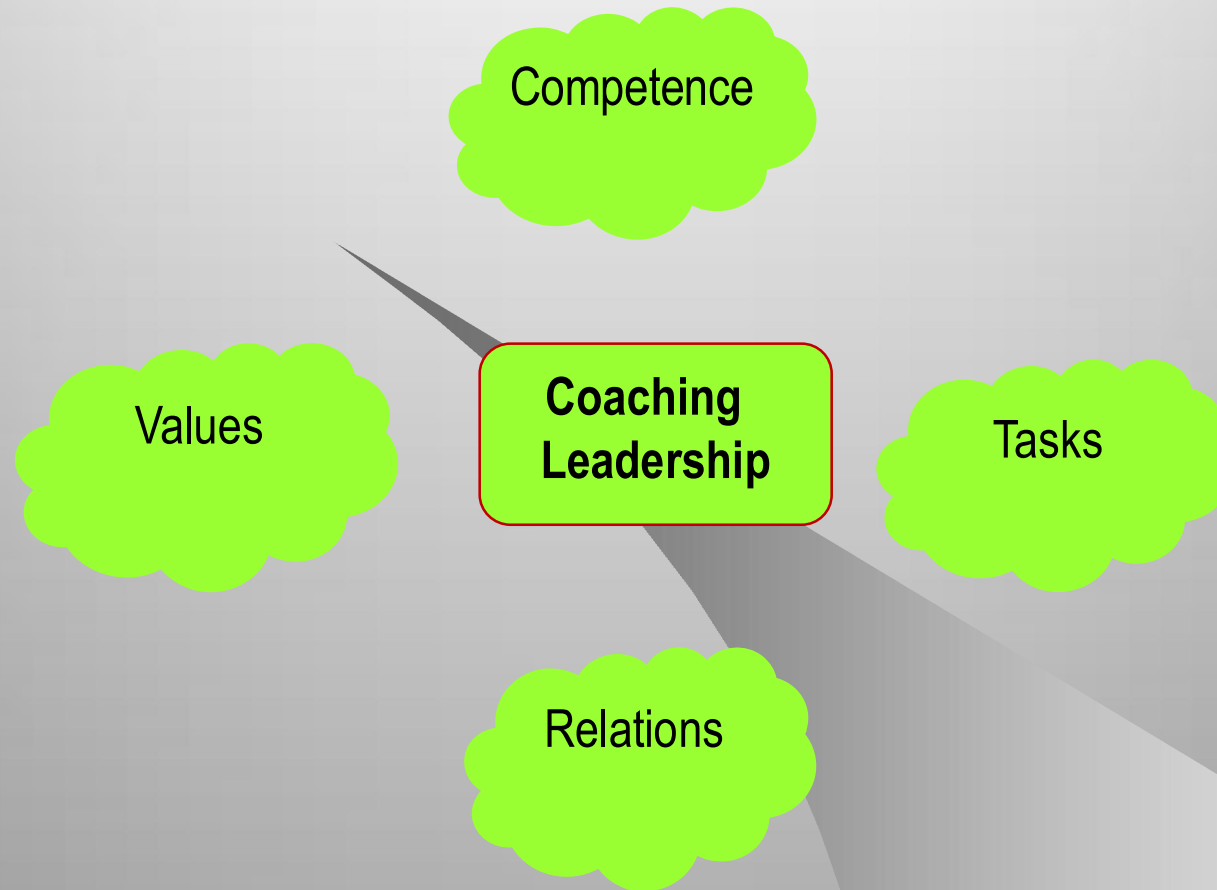
But not only...

Leadership Dimensions, Roles and Profiles

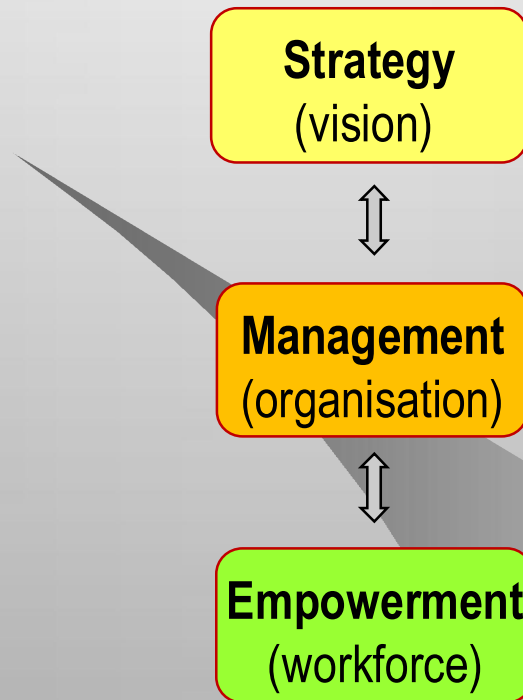


But not only...

Leadership Dimensions, Roles and Profiles

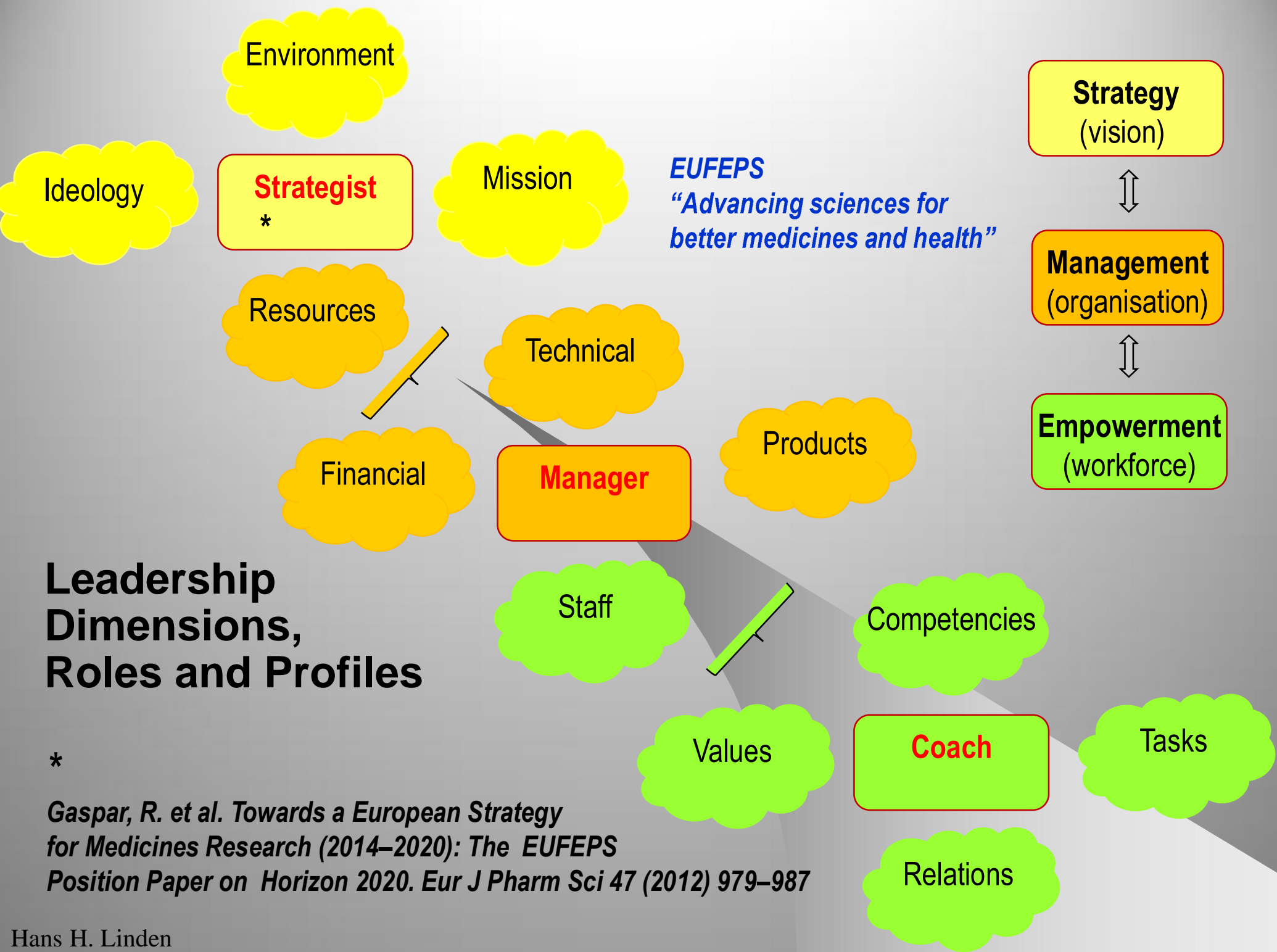


Leadership Dimensions, Roles and Profiles



Leadership Dimensions, Roles and Profiles





Leadership Dimensions, Roles and Profiles

*
 Gaspar, R. et al. *Towards a European Strategy for Medicines Research (2014–2020): The EUFEPS Position Paper on Horizon 2020. Eur J Pharm Sci 47 (2012) 979–987*

Strategy

high level plan to achieve one or more goals under conditions of uncertainty

Management

the function that coordinates the efforts of people to accomplish goals and objectives using available resources efficiently and effectively

Coaching

training or development in which a person called a "coach" supports a learner/s in achieving a specific personal or professional goal

occasionally, a relation between two people, of whom one has more experience and expertise than the other, offering advice and guidance, but different from mentoring, which focusses on competence specifics, as opposed to general overall development

Where is leadership needed?

What leadership is needed?

When is leadership needed?

Are you as person and leader a strategist, manager or coach, primarily?

Competencies Foundation – Education and Training



Any needs?

**Research
Substance**

Competencies Foundation – Education and Training



**Research
Substance**

**Development
Delivery**

Competencies Foundation – Education and Training



**Research
Substance**

**Development
Delivery**

**Processing
Manufacturing**

Competencies Foundation – Education and Training



**Research
Substance**

**Development
Delivery**

**Processing
Manufacturing**

**Usage
Distribution**

Competencies Foundation – Education and Training



Legal and Regulatory Framework – Window of Operation

Research
Substance

Development
Delivery

Processing
Manufacturing

Usage
Distribution

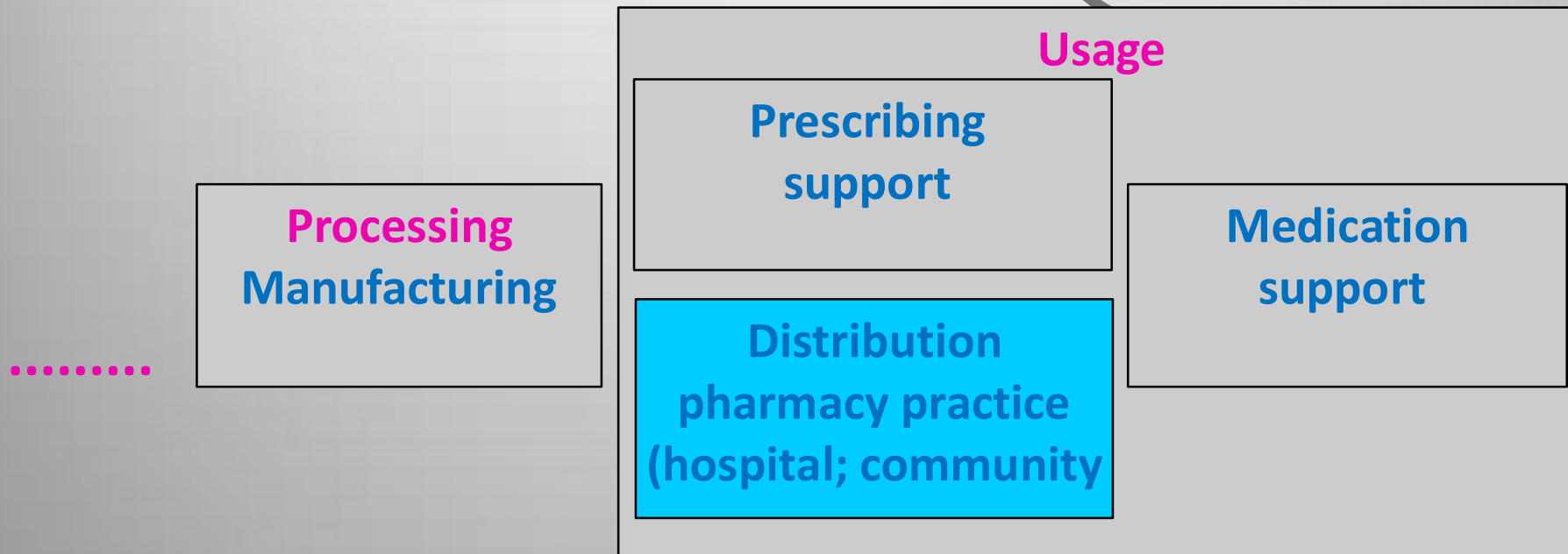
Competencies Foundation – Education and Training



Sciences based, or needs driven, or both?

Medicines research, development, processing and usage ...

Legal and Regulatory Framework – Window of Operation

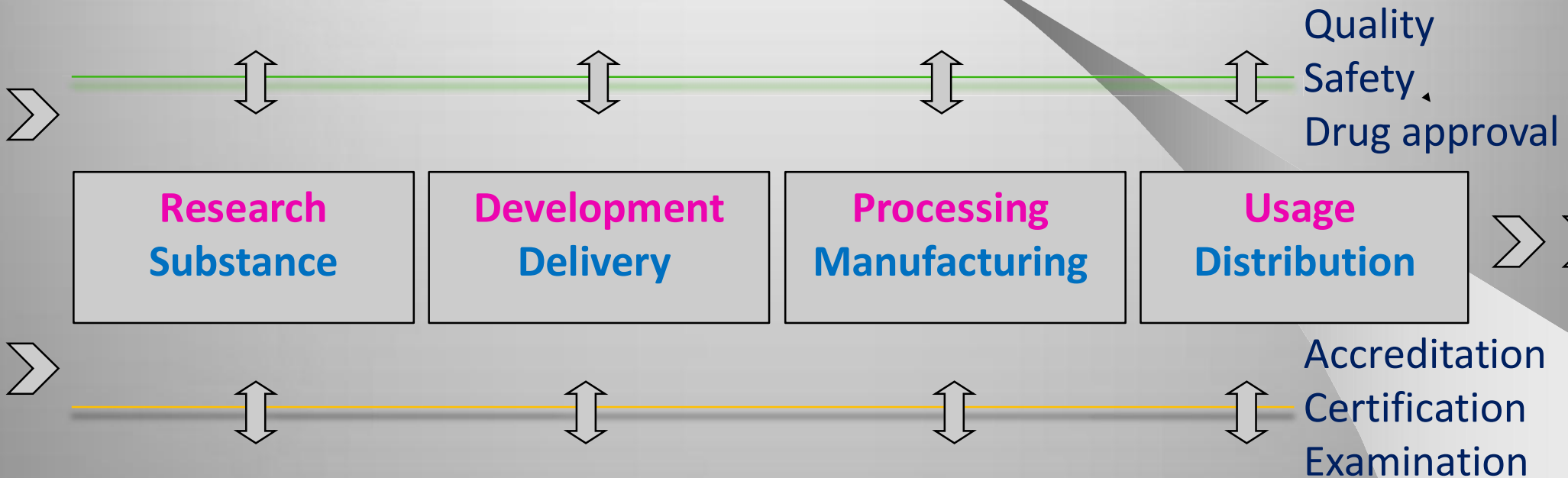


Competencies Foundation – Education and Training



Medicines research, development, processing and usage ...

Legal and Regulatory Framework – Window of Operation



Research
Substance

Development
Delivery

Processing
Manufacturing

Usage
Distribution

Competencies Foundation – Education and Training



Qualitatively different phases and roles in drug discovery, development, processing and usage of medicines

Medicines research, development, processing and usage the system

Legal and Regulatory Framework – Window of Operation

Quality
Safety
Drug approval

Research
Substance

Development
Delivery

Processing
Manufacturing

Usage
Distribution

Accreditation
Certification
Examination

Competencies Foundation – Education and Training

Qualitatively different phases and roles in drug discovery, development, processing and usage of medicines

Any needs?



Challenge for Change...

Identifying and making use of all possible resources and efficiently integrating it all into an effective flow.

Will it happen by itself? Probably not.

A vision (“something seen in a dream”) might be the start; then transforming it into a clear strategy, good management, and persistent team support.

What would be our **unique contribution** to the system as leaders, educators, trainers and professional community?

EUFEPS Committee on Industrial Research Relations (CIRR) 2003

Big concern that academic training in relevant toxicology were closing down in many universities and/or reduced in curricula





NEWS

Letter

European Federation for Pharmaceutical Sciences March Vol 12 No1 2003

Executive Committee

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- Croatia

‘Safety Sciences’

– a way out of the attrition dilemma

The EUFEPS Committee on Industrial Relations (CIR) produced this discussion paper and presented it at a recent meeting of the EUFEPS Executive Committee, who wanted to see it published. Moreover, the Committee strongly supports the CIR in urging you - from academia, industry and regulatory - to read it and to open a discussion on "safety sciences and the attrition dilemma". (Editor: why not in this Newsletter?)

detection and risk management before the costly clinical development phases start. However,



June 2004 Report from EUFEPS Brainstorm Workshop on Safety Sciences



EUROPEAN FEDERATION FOR PHARMACEUTICAL SCIENCES

Report from EUFEPS Brainstorm Workshop on

Safety Sciences

Brussels • April 2-3 • 2004

June 29, 2004

Initiated by the EUFEPS Committee on Industrial Research Relations (CIRR)



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'Safety Sciences'

- 2004: EUFEPS Brainstorm Workshop (I) on Safety Sciences, and Outcomes Report – presented to the Research Directorate of the European Commission; funded by EUFEPS and a sponsor, addressing the foreseen short-fall of “safety sciences”
- 2005: EUFEPS Expert Meeting on Drug Safety
- Drug research considered, by the European Commission, as a priority in the 7th RTD Framework Programme (FP), including education and training, 2007 –
- Vision and strategy emerging: Education and Training for a “new breed” of safety scientists, if funding for it in the FP7 Innovative Medicines Initiative Joint Undertaking (IMI JU)
- 2007: EUFEPS Workshop (II) on Development and implementation of European Education and Training Programmes, leading up to an Expression of Interest (EoI) and proposed IMI JU Project
- 2010: Start of SafeSciMET project 2010-14; extended to 2016





Safety Sciences for Medicines Education and Training

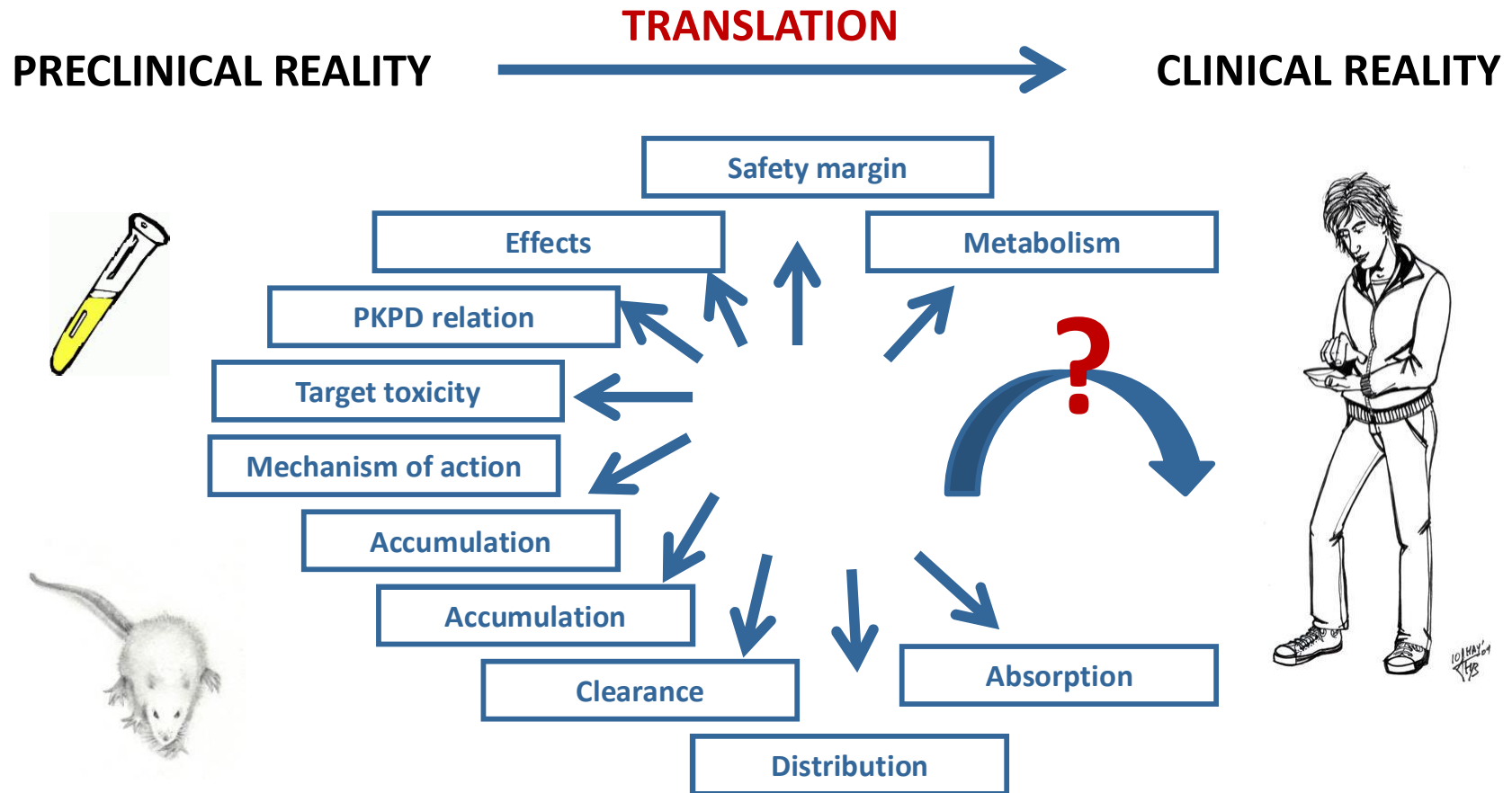
Focus

“Safety issues are major reasons for discontinuing otherwise promising drug candidates from pharmaceutical development of new medicines”

“Today’s education and training of safety scientists and specialists need a stronger focus on the **development and application of new achievements and methodologies**”

Safety Sciences

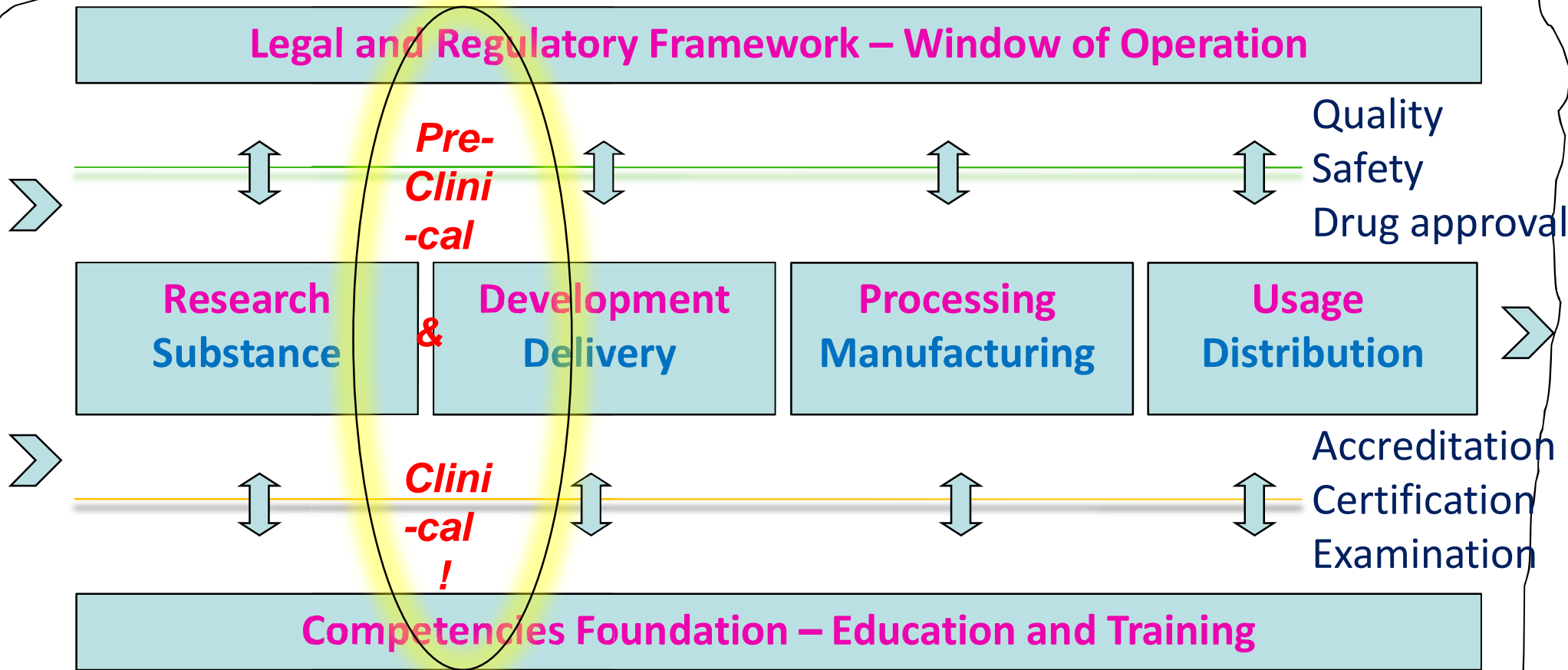
integration and translation



Medicines research, development, processing and usage ... the system



Safety Sciences in...

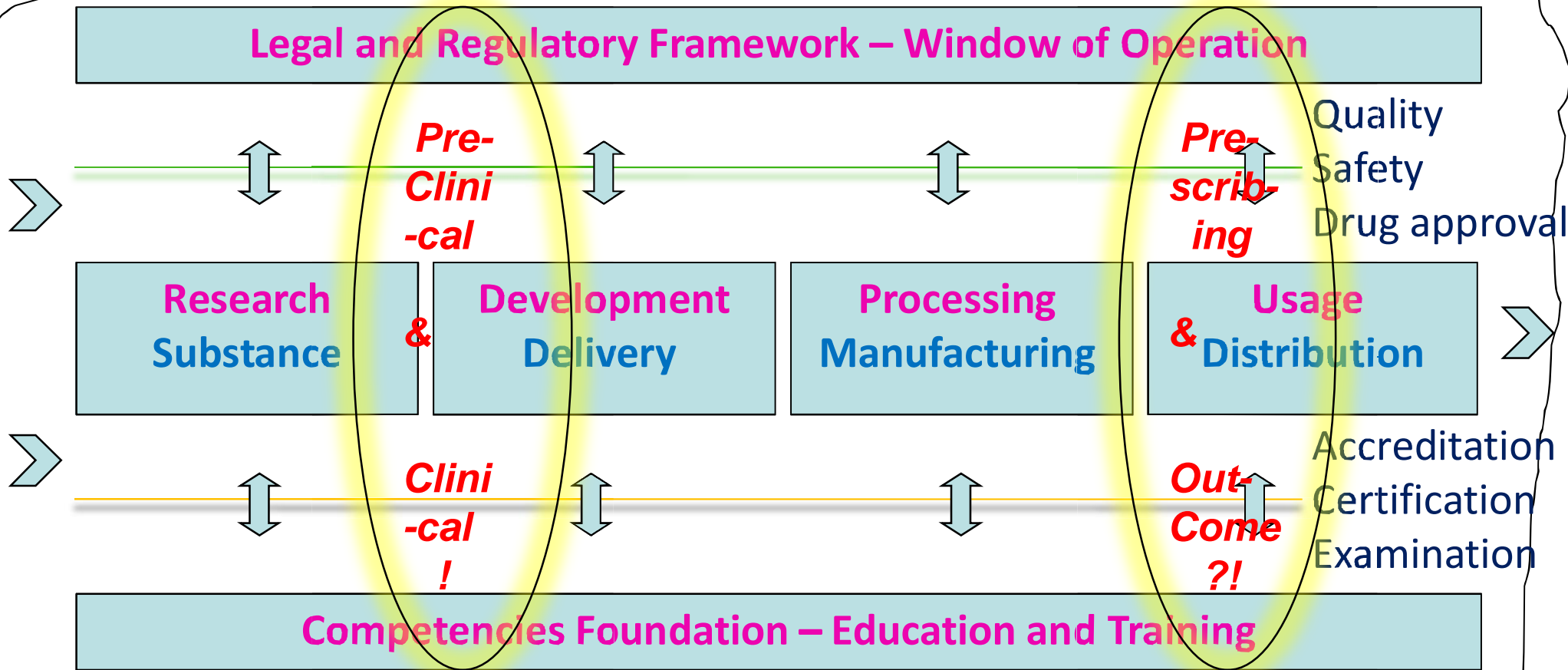


Qualitatively different phases and roles in drug discovery, development, processing and usage of medicines

Medicines research, development, processing and usage ... the system



Safety Sciences in...



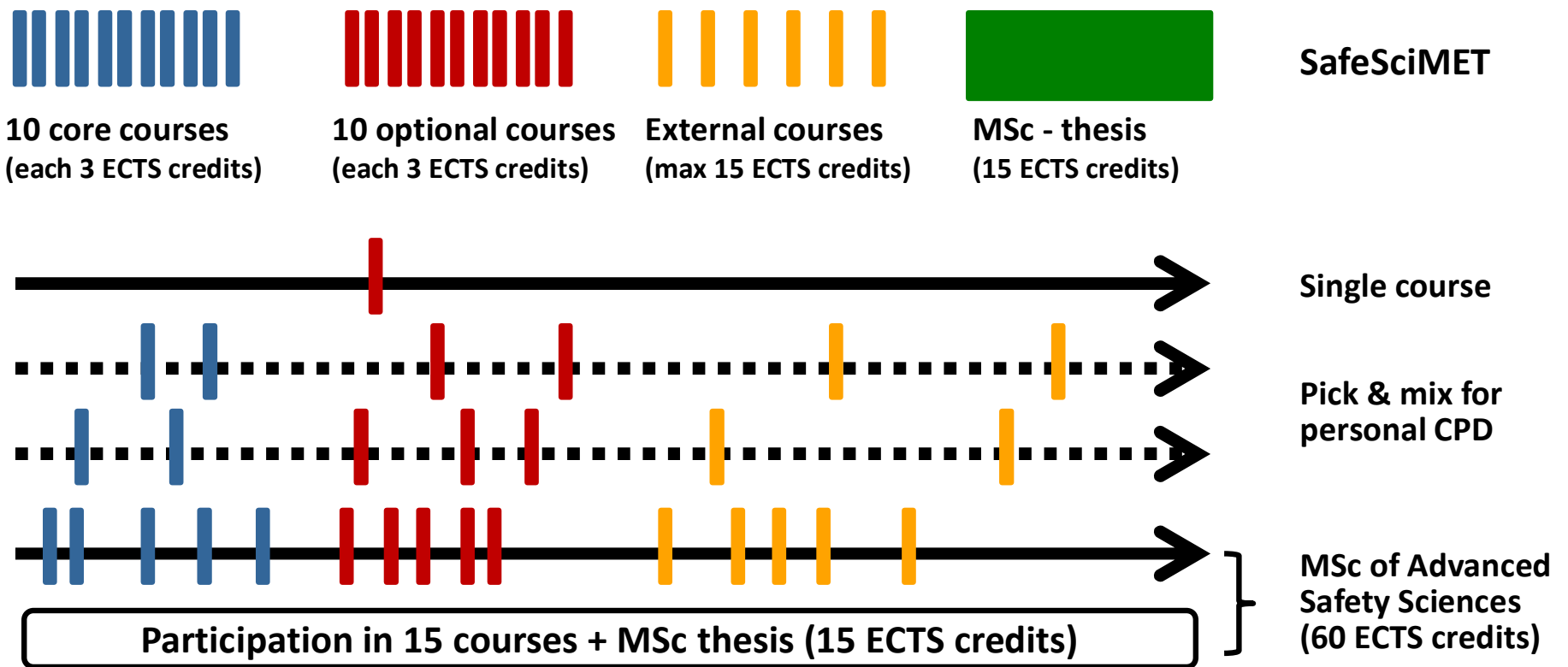
Qualitatively different phases and roles in drug discovery, development, processing and usage of medicines



Safety Sciences

goals and outcomes – 20 new courses

European Modular Education and Training Programme in Safety Sciences for Medicines



Accredited as Master's Programme in Advanced Safety Sciences for Medicines, by the University of Konstanz, Germany

www.safescimet.eu

IMI Education and Training Projects



European Medicines Research Training Network



Pharmaceutical Medicine Training Programmes



European Modular Education and Training Programme
in Safety Sciences for Medicines

IMI-TRAIN
common portal
Joint project
2015-16
www.imi-train.eu





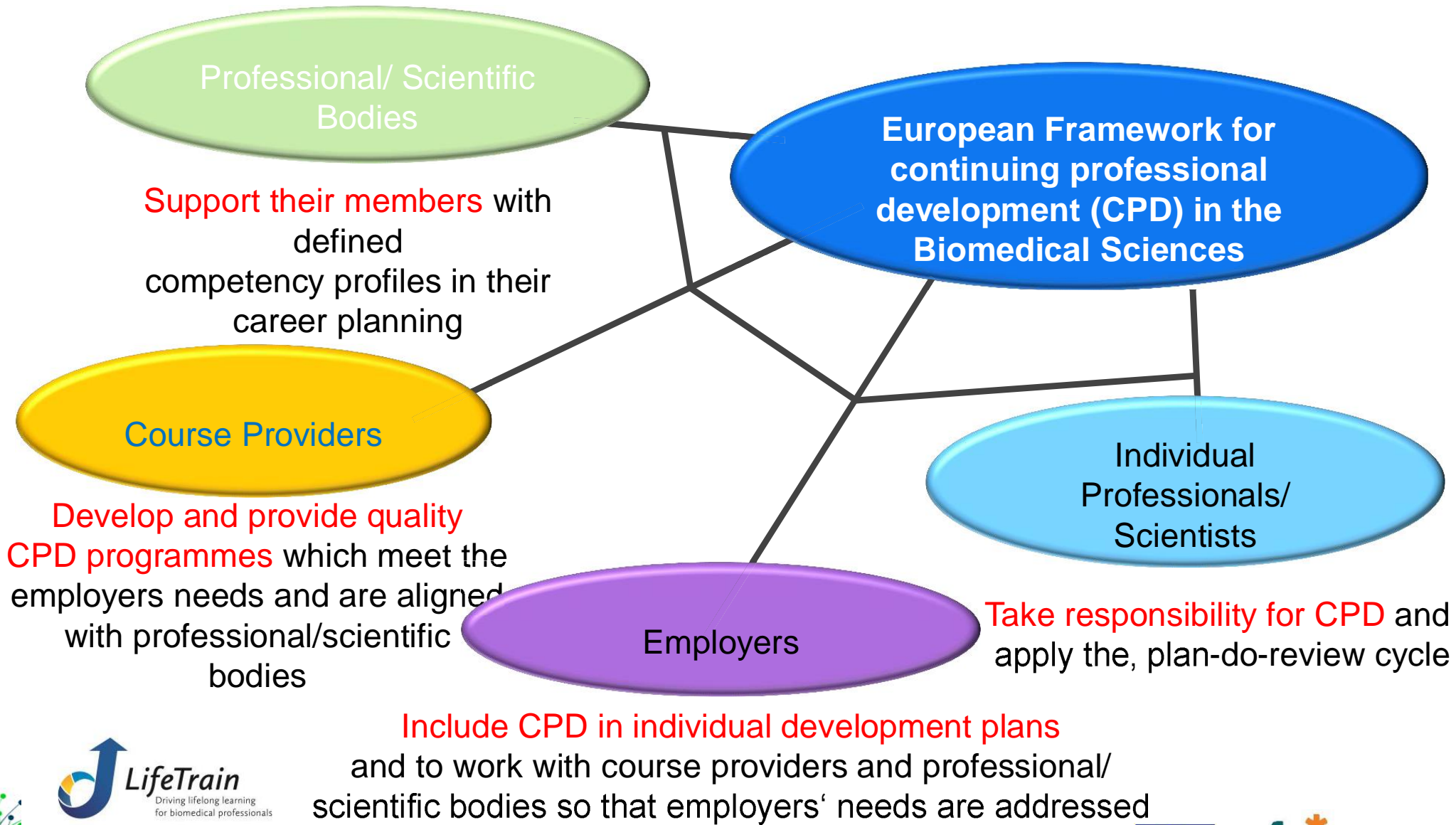
A double rod pendulum animation showing chaotic behavior. Starting the pendulum from a slightly different initial condition would result in a completely different trajectory. The double rod pendulum is one of the simplest dynamic systems that has chaotic solutions.

<http://en.wikipedia.org/wiki/File:Double-compound-pendulum.gif>

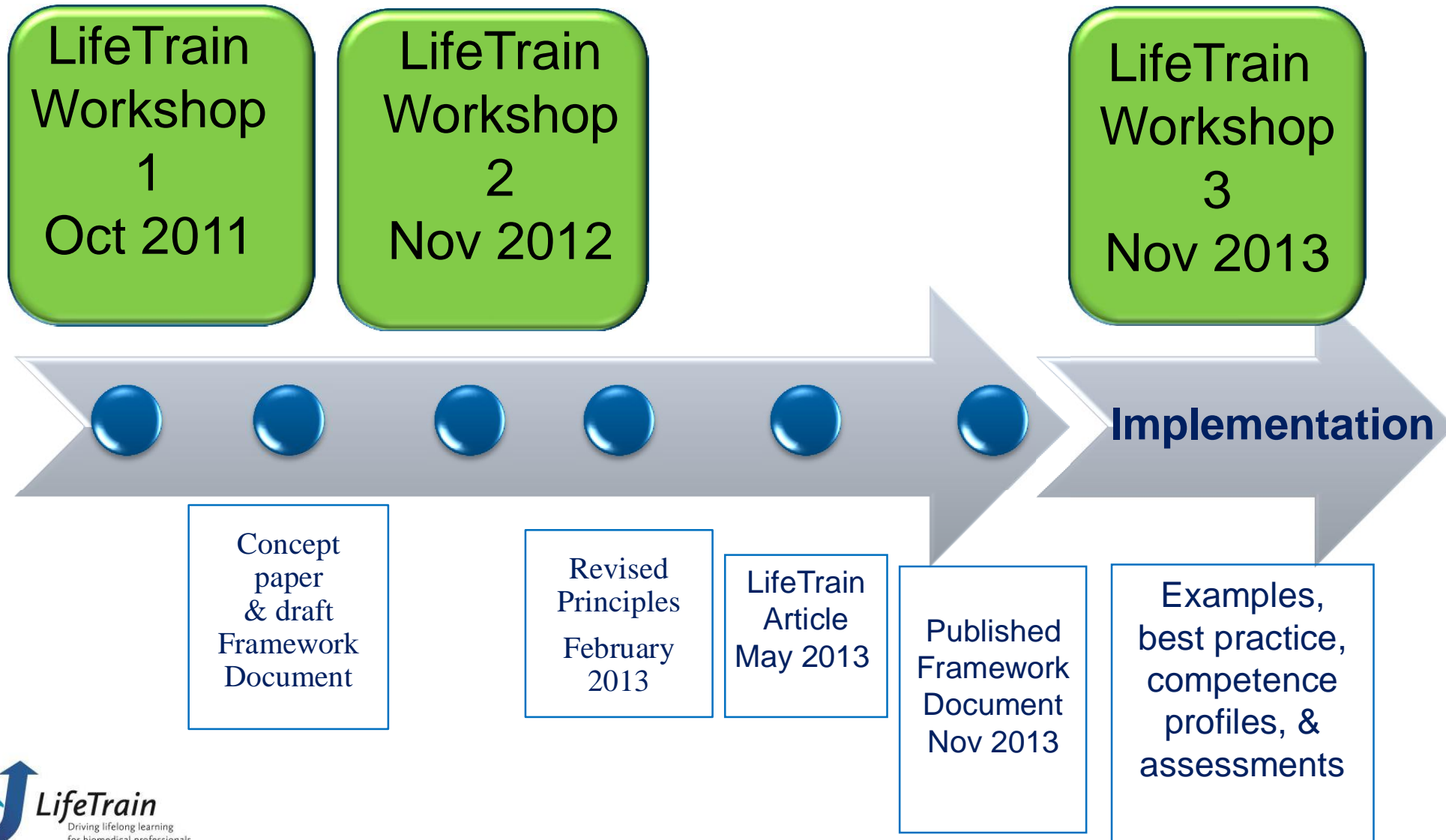
Every professional in the biomedical sciences needs to **develop and maintain** an optimal level of professional competence, to speed up the development of better medicines for patients



The LifeTrain Framework



The LifeTrain Journey



LifeTrain's key messages

- Every professional in the biomedical sciences needs to develop and maintain an optimal level of professional competence in order to contribute to speeding up the development of better medicines for patients.
- An individual competency portfolio should capture all relevant information in a transparent, easy-to-understand way in order to facilitate mobility between: scientific disciplines; academia, health authorities and industry; jobs and countries; and to support career development.
- Continuing professional development (CPD) is essential and should be driven by each individual in agreement with their employer and in compliance with the requirements of the respective professional/scientific bodies.
- CPD should be part of a “plan, do, review” cycle and can include formal, non-formal and informal learning. Each individual should reflect on the learning and its application in practice.
- Objective assessments of competence should be made by the individual and by others, on a regular basis throughout the individual's professional working life.
- Needs should be identified and professional training courses developed and delivered in collaboration between industry, technical experts, and course providers (including universities). They should meet the needs of adult-learners and should be available on on-course®.

The signatories to this European Common Framework for CPD in the biomedical sciences have agreed to the principles of the framework and to continue the collaboration in the implementation process.

European Common Framework for
Continuing Professional Development
in the Biomedical Sciences

Developed by LifeTrain



*Biomedical sciences" includes ALL science disciplines involved in the discovery, development, processing and usage of medicines research, including supporting technologies

- 80+ signatories, currently
- on-course® biomedical postgraduate course portal
- IMI Education and Training Shared Quality Standards
- Volunteer commitments bulleted for
 - ✓ “Professional/scientific bodies will...”
 - ✓ “Employers will ...
 - ✓ “Course Providers will ...”
 - ✓ “Individual Professionals will ...”
- Competency profiles searched and (20) listed (on website)
- Competencies in safety sciences drafted – 100+ suggested ones consolidated to 35 in 7 domains for 15 job roles
- Consultation round started (among 70 experts and specialists)
- Open LifeTrain Workshop, on July 5-7, 2016, Heidelberg, Germany, sponsored by EMBL

Where from here?

*People have thought about it and
there are high-level commitments
to help and support.*

IMI – Europe's Partnership for Health

IMI 1 Programme 2008-2013

- €2 bn budget
- 11 Calls for proposals
- 50+ projects

IMI 2 Programme 2014-2024

- Larger budget
- Ambitious Strategic Research Agenda
- Open to other industries

IMI 2 total budget
€3.28 bn



€1.638 bn

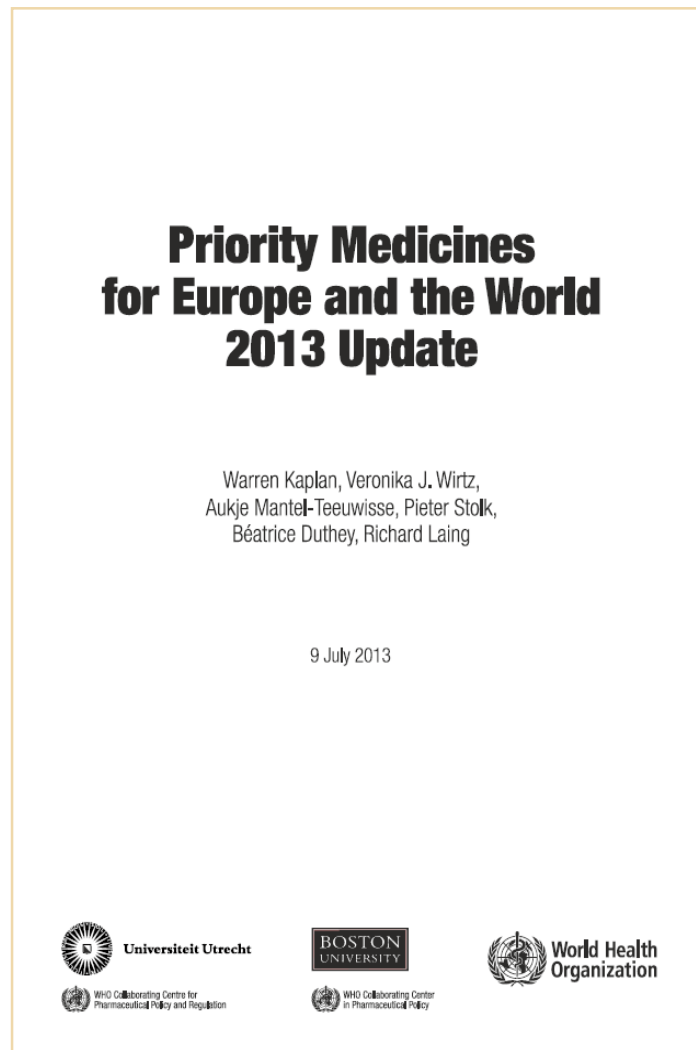


€1.425 bn

Other

€213 m

IMI 2 Strategic Research Agenda



Goals of the IMI 2 Programme

- Increase the success rate of **clinical trials** of new medicines & vaccines
- Speed up the **earlier stages** of drug development
- Develop new treatments for areas of **unmet need**
- Develop new biological markers to **diagnose** diseases and **assess treatments**
- Improve the drug development process by creating tools to assess the **efficacy, safety and quality** of medicines

www.imi.europa.eu

IMI 2 Priorities

Priority Themes

1. Neuro-degeneration
2. Immuno-inflammation
3. Metabolic disorders
4. Infection control
5. Translational Safety

Support Technologies

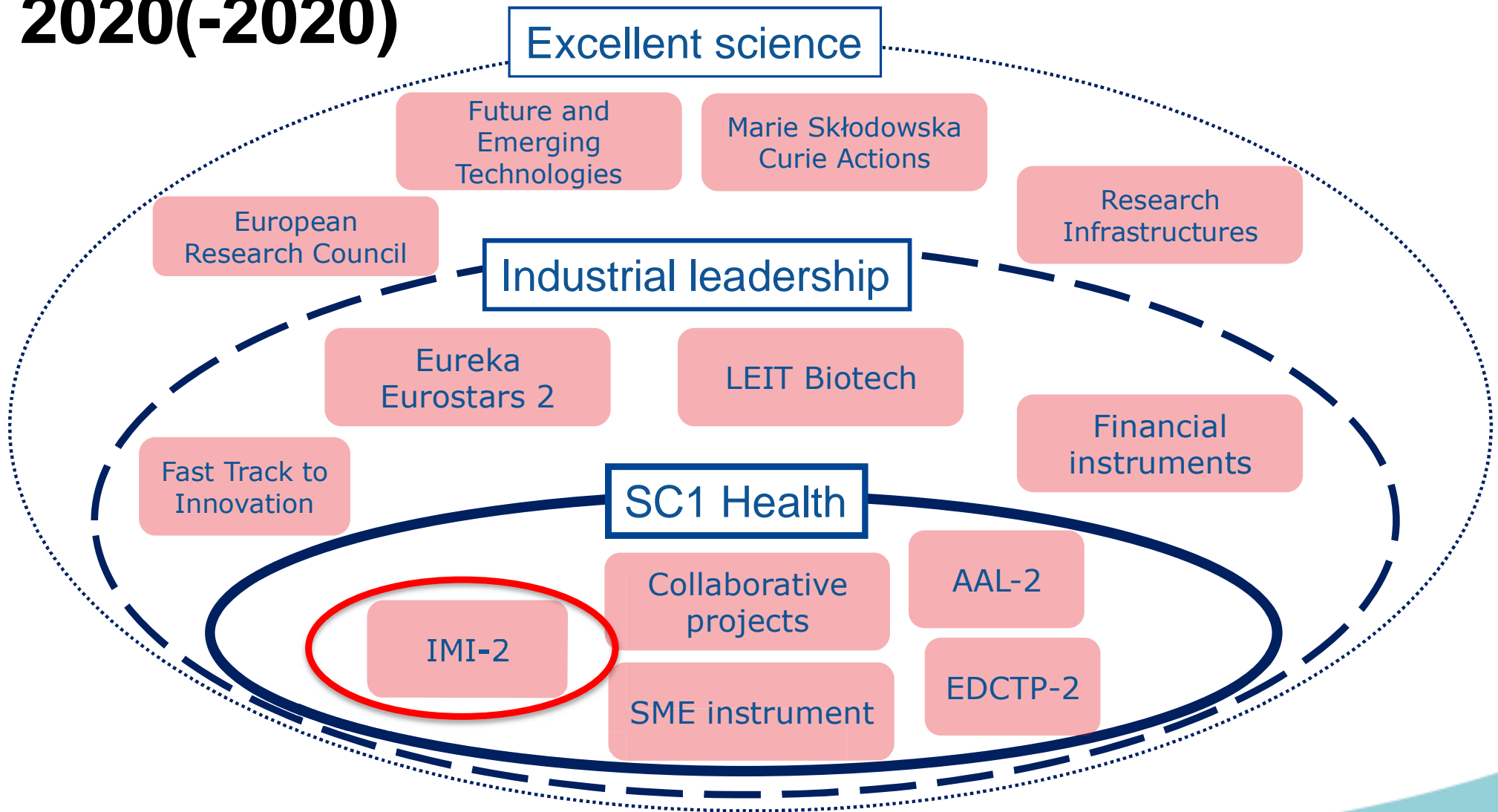
1. Imaging
2. ICT
3. Medical devices....

Enablers

Patient access to innovative solutions (Medicines Adaptive Pathways to Patients - MAPPs)

- Target validation
- Stratified medicine, precision medicine
- Innovative trials
- Data generation and interpretation
- Prevention, disease interception
- Patient adherence
- Health disease management
- Regulatory framework
- Reimbursement/patient access

Funding instruments for health research in the EU funding programme Horizon 2020(-2020)

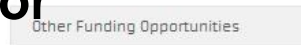
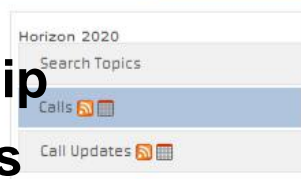
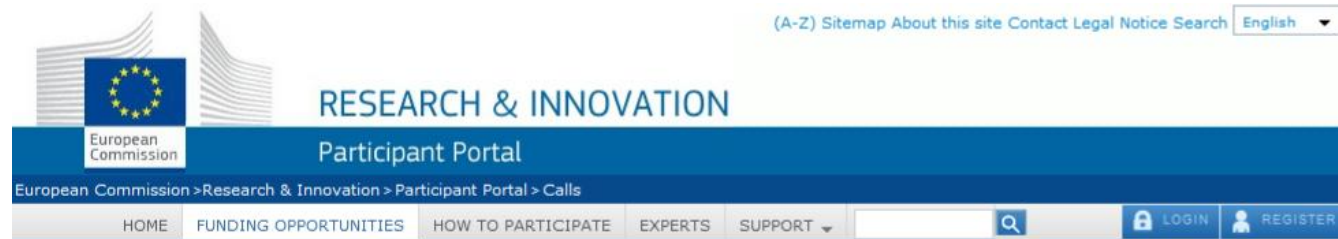


EU Public-Private Partnerships for R&I

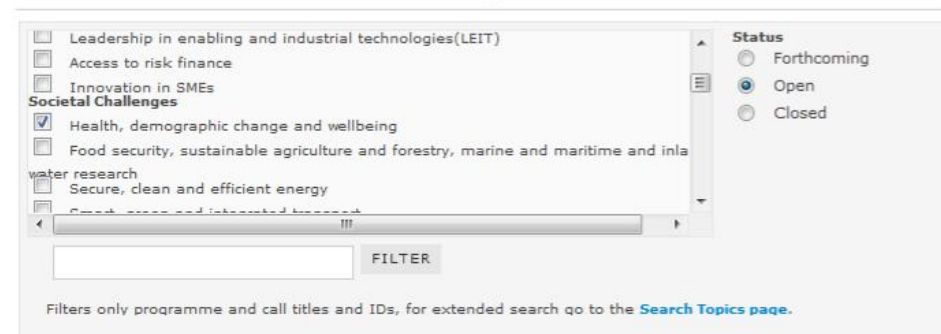
- 5 "Joint Technology Initiatives":
 - **Innovative Medicines Initiative 2 (IMI2)**: to develop next generation vaccines, medicines and treatments, such as new antibiotics
 - **Fuel Cells and Hydrogen 2 (FCH2)**: to expand the use of clean and efficient technologies in transport, industry and energy
 - **Clean Sky 2 (CS2)**: to develop cleaner, quieter aircraft with significantly less CO2 emissions
 - **Bio-based Industries (BBI)**: to use renewable natural resources and innovative technologies for greener everyday products
 - **Electronic Components and Systems (ECSEL)**: to boost Europe's electronics manufacturing capabilities
- Total investment 2014-2020: €17.5 billion (of which € 6.5 billion from the EU Programme Horizon 2020)

Finding information about Horizon 2020 funding opportunities incl. IMI2

- Three main parts
 - ✓ Excellent science
 - ✓ Industrial leadership
 - ✓ Societal challenges
- Special focus on “Health, demographic change and wellbeing”
- Research driven
- Needs driven
- Bottom up
- Specific SME instrument for European companies



Horizon 2020 Calls for Proposals



Sort by	Title	Call Id	Planned Opening Date	Deadline Date
Societal Challenges	Personalising health and care	H2020-PHC-2015-single-stage_RT	Deadlines: 24/02/2015 Opening Date: 30/07/2014	Deadlines: 14/10/2014 Opening Date: 30/07/2014
Societal Challenges	Personalising health and care	H2020-PHC-2015-two-stage	Deadlines: 21/04/2015 Opening Date: 30/07/2014	Deadlines: 21/04/2015 Opening Date: 30/07/2014
Societal Challenges	Health Co-ordination Activities	H2020-HCO-2015	Deadlines: 24/02/2015 Opening Date: 30/07/2014	Deadlines: 24/02/2015 Opening Date: 30/07/2014
Societal Challenges	IMI2 1st Call for Proposals 2014	H2020-JTI-IMI2-2014-01	Deadlines: 12/11/2014 Opening Date: 09/07/2014	Deadlines: 12/11/2014 Opening Date: 09/07/2014
Industrial Leadership	Horizon 2020 dedicated SME Instrument - Phase 2 2014	H2020-SMEINST-2-2014	Deadlines: 09/10/2014 17/12/2014 Opening Date: 03/03/2014	Deadlines: 09/10/2014 17/12/2014 Opening Date: 03/03/2014
Industrial Leadership	Horizon 2020 dedicated SME Instrument - Phase 1 2014	H2020-SMEINST-1-2014	Deadlines: 18/06/2014 24/09/2014 17/12/2014 Opening Date: 03/03/2014	Deadlines: 18/06/2014 24/09/2014 17/12/2014 Opening Date: 03/03/2014



- EU Research
- Participants Portal

*What from now on and beyond these frameworks?
How to approach?*

*We should take the lead in our field or fields – and go. **Together.***

See to that the leadership dimensions needed are well represented in it.

“

Three main parts

- ✓ Excellent science
- ✓ Industrial leadership
- ✓ Societal challenges

Special focus on “Health, demographic change and wellbeing”

Research driven

Needs driven

Bottom up

Specific SME instrument for European companies

”

Medicines, Consumers and Pharmacy

Medicines are borderless

- As manufactured and available on the (global) market

Many consumers are too

- As free to travel, move and migrate

Pharmacy practice perhaps not yet

- Since national regulation and (local) tradition

What for all; what since nationals

- For any patient anywhere/from anywhere

Effective Executive Steps...

1. Identify and define the *real* problem/s and needs
2. Define and localise target audiences or people
3. Assess their needs as well by listening to them
4. Arrive at (detailed) objectives for any operation
5. Pick and/or design actions to fill gaps and move
6. Identify individuals and organisations willing to help to implement (and fund) actions, and get them involved, including yourself, if/as needed
7. Make sure that all understand the significance of their particular contribution
8. Establish pathways for feedback and evaluation

Three conclusions by P.F. Drucker...

***“Efficiency is doing things right;
effectiveness is doing the right things”***

***“If you want something new, you
have to stop doing something old”***

***“The best way to predict the future
is to create it”***

Peter F. Drucker was a writer, professor,
and management consultant (1909-2005)



Thank you!

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European Federation for Pharmaceutical Sciences



Established in 1991