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EurSci4Health Stakeholder Workshop

"Public Health"

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K1 Competence Center - Initiated by the Federal Ministry of Transport, Innovation and Technology (BMVIT) and the Federal Ministry of Science, Research and Economy (BMWFW).
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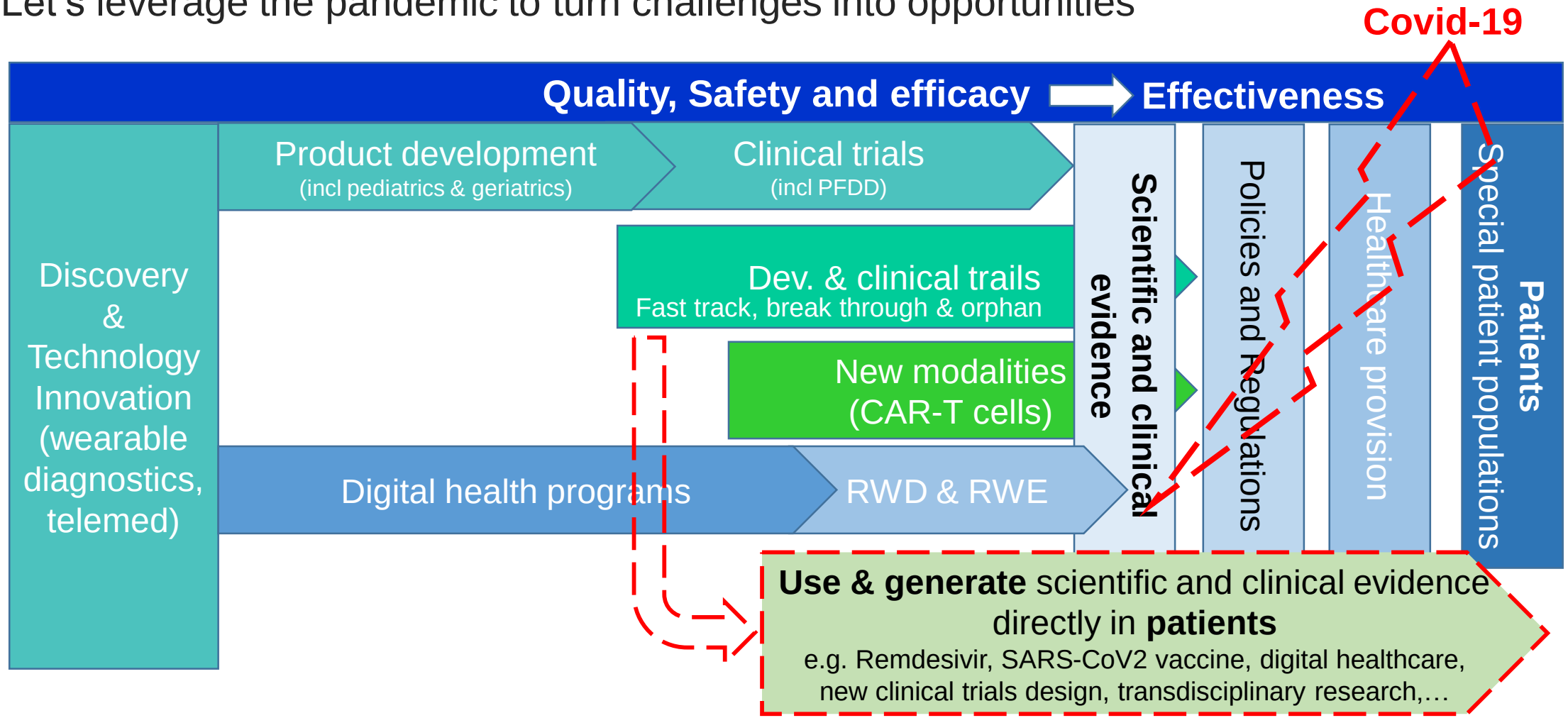
Introduction

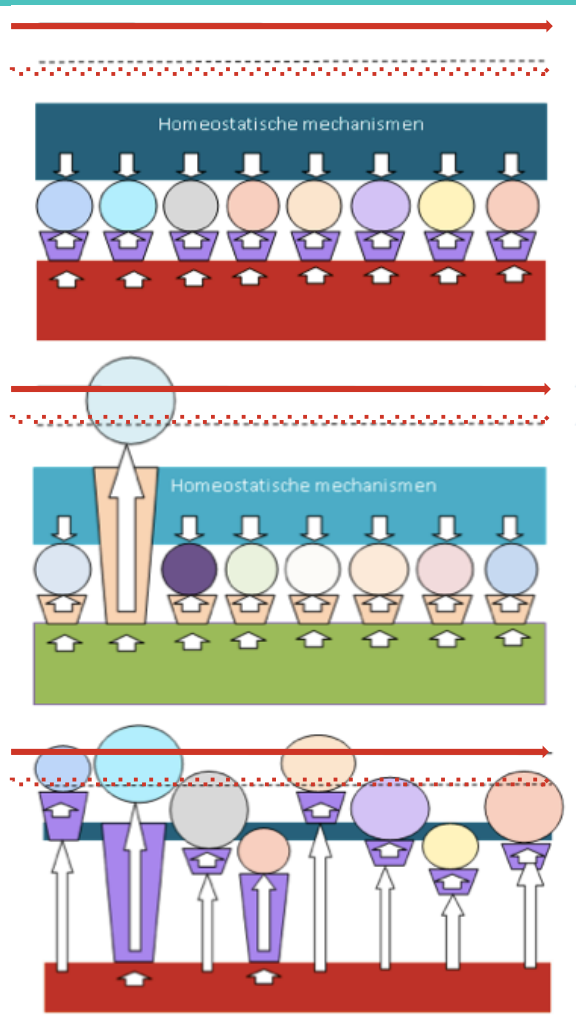
Let‘s leverage the pandemic to turn challenges into opportunities



Challenge 1: Increasingly older and multimorbid patients

Prescribing to older and multimorbid patients is an emerging challenge

- Have complex clinical patterns [1]
- Shared decision making – priority on QoL (wellbeing, satisfaction, postive life balance, future life perspective, social participation , active daily organization, environmental support) [2]
- Request for physician-assisted death in Belgium grew between 2007 to 2013 from 3.4 % to 5.9 % and the granted requests from 1.9 % to 4.6 % [3]
- Increasing ethical issue to decide (doctors & society) when to terminate efforts to keep people alive [4]



Limits for clinical evaluation

Limits of disaeses

Young - Non chronic diseases

Young - Vital - Acute illness

Old - Frail - Multimorbide

1. *Olde Rikkert MGM, EAMA 2015*
2. Kada et al ZGG 51:628 (2018)
3. Dierickx et al JAMA Intern Med 2015
4. Truog RD – JAMA 319; 18 (2018)

Challenge 2: Increasing therapeutic complexity

A multimorbid patients‘ perspective

- A paradox situation
  - Increasing therapeutic complexity:
    - 7 „dosing moments“
    - 30 min before breakfast
    - 1 - ½ - 1 tablet schedules
  - Declining management capabilities: cognitive, dexterity, grip strength,…[1]

- **The patient as the user is the major, final factor for safety & effectiveness**

	Morning	Noon	Evening	Night	Drug Form	Instructions to use
Moxonidin (0.3 mg)	1				Tablet	
Tyronajod (125µg)	1				Tablet	30 ‘ before breakfast, glas of water
Tamsulosin 0.4 mg)	1				HGC	
Furosemid (40 mg)	1	1			Tablet	30’ before breakfast
Nifedipine 5 mg)	1	1	1		SGC	With meal
Enalapril (20 mg)	1		½	1	Tablet	
Propiverin 15 mg)	1		1	1	Tablet	With meal
Lithiumcarbonate 450 mg)	½		½		MR Tab	
Vitamin D 20000IE		1 week			SGC	Once a week with fat meal
Allopurinol 300 mg)		⅓		1	Tablet	
Omeprazole (20 mg)	1				MR Tab	30’ before breakfast
Vertigogeel	2	2	2		Subling	Dissolving sublingual

Typical example: 75 year old patient Asthma, diabetes type 2, coronary heart disease, RLS, leg edema, lumbosciatica

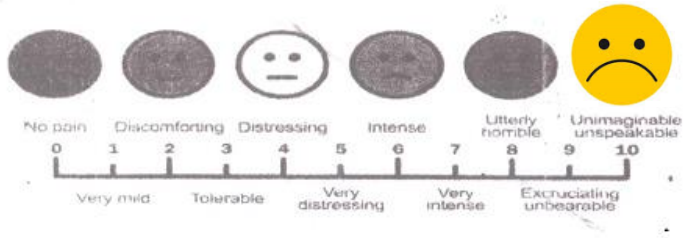
1. Shippee et al J Clin Epidemiol 65:1041 (2012)

Challenge 2: Increasing therapeutic complexity

Real case from practice

Medication schedule to manage pain prescribed

- Purely oriented to scientific evidence gained in RCT
- Omits the effect of good sleep, social interaction, avoidance of stress etc. on pain
- The therapeutic process is beyond clinical parameters



Morning: 6:00 – 7:30 – 8:00 – 9:00
Noon: 12:00 – 14:00 – 15:00
Evening: 18:00 – 20:00 – 21:00
Night: 00:00 – 03:00
12 Dosing moments!

Schmerzmittel *(painkillers)*

SERACTIL 400 mg (300 mg / 200 mg)
(Dexibuprofen)

1	0	1	0
8:00		20:00	

Alternative: Ibuprofen, Brufen, Proxen, Naproxen, Naprobene, Diclobene

MEXALEN 500 mg
(Paracetamol)

1	1	1	1
6:00	12:00	18:00	00:00

Alternative: Panodil, Dafalgan, Panadol, Perfalgan

NOVALGIN 500 mg
(Metamizol)

1	1	1	1
9:00	15:00	21:00	03:00

Alternative: Analgin, Berlosin, Minalgin, Nopain, Nolotil

Magenschutz *(stomach protection)*

PANTOLOC 20 mg (40 mg)
(Pantoprazol)
Alternative: Pantoprazol, Rabeprazol,

1	0	0
7:30		

Gegen Schwellung *(against swelling)*

WOBENZYM
(Pflanzliche Enzyme (plant enzymes)
Alternative: Karazym, Phlogenzym

5	5	5
8:00	14:00	20:00

Krampfprophylaxe *(against muscle cramps)*

MAGNOSOLV GRANULAT
(Magnesium)
Alternative: Magnesium Verla

0	0	1
		20:00

Thromboseprophylaxe *(against thrombosis)*

LOVENOX 40mg (20mg / 60mg)
(Enoxaparin, NM- (LMW-) Heparin)
Alternative: Fragmin, Fraxiparin, Ivor,

1	0	0
8:00		

Challenge 3: Importance of the patient perspective

- Disease burden
- Therapeutic burden
- QoL

- Motoric
- Sensoric
- Cognition
- Psychological
- Visual
- Hearing
- Saliva
- Taste

- PK/PD changes
- Multimorbidity
- Vulnerability
- DDIs, ADRs
- Frailty-Syndrom
- Homeostasis

- Life perspective
- Personal wishes
- Social support

Challenge 4: Transfer of responsibility for therapy execution

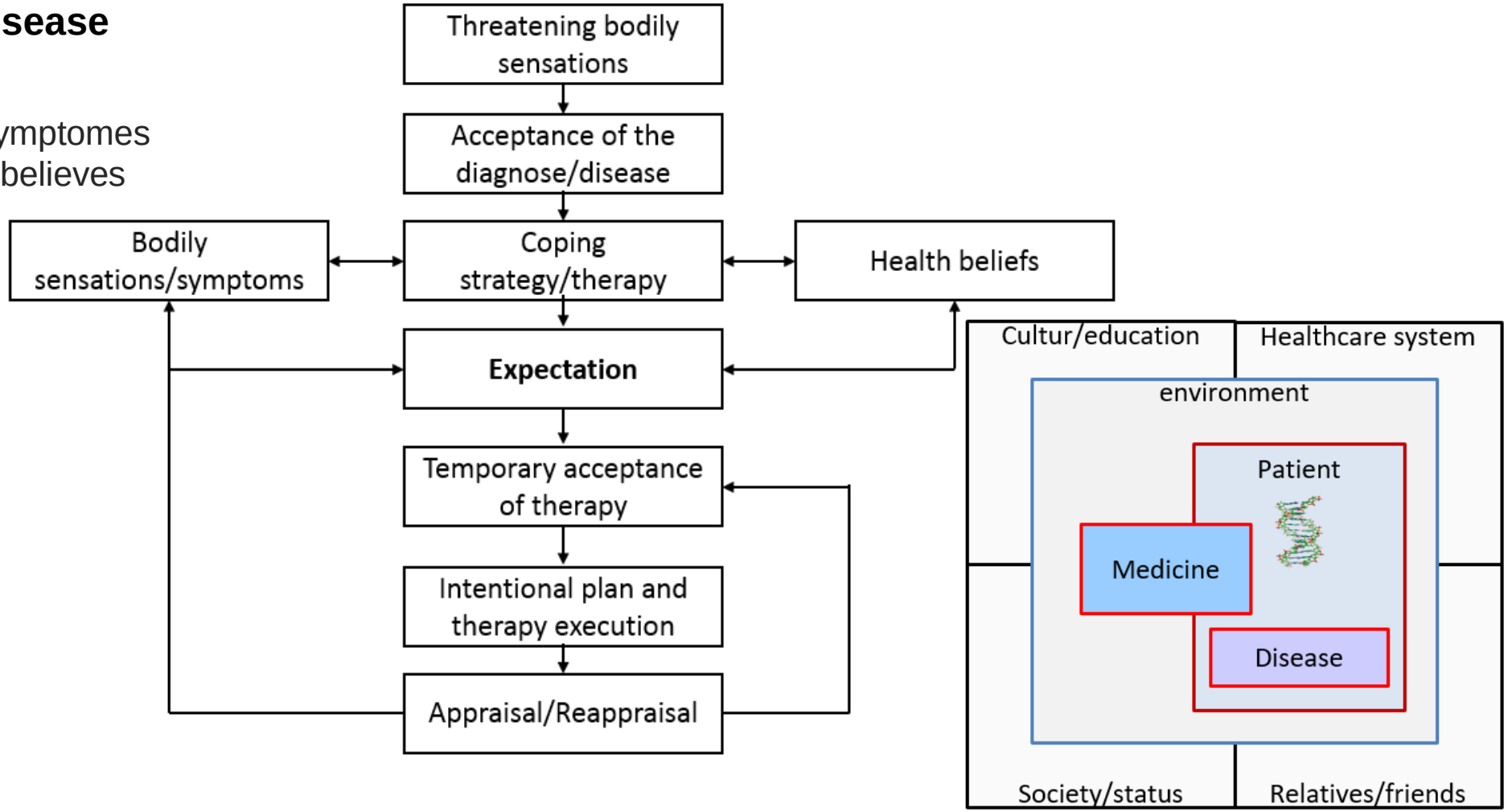
1. Acceptance of the disease

2. Patient expectation
- Effect bodily sensation/symptomes
- Compatibility with health believes
- Product perception and experience

3. Implementation plan

4. Reappraisal

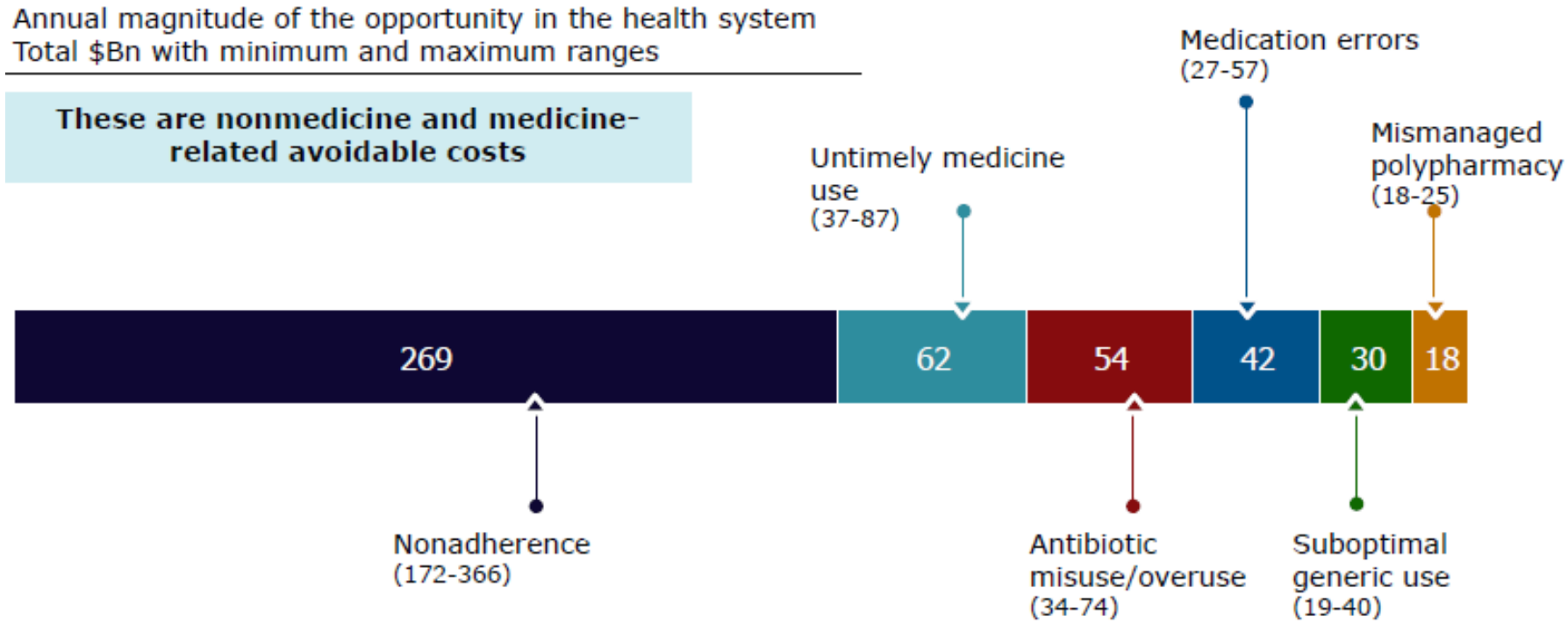
5. Illusion of control



Stegemann S In: Developing drug products in an aging society, pp 153-170 (2016)

Challenge 5: Pressure on healthcare systems efficiency

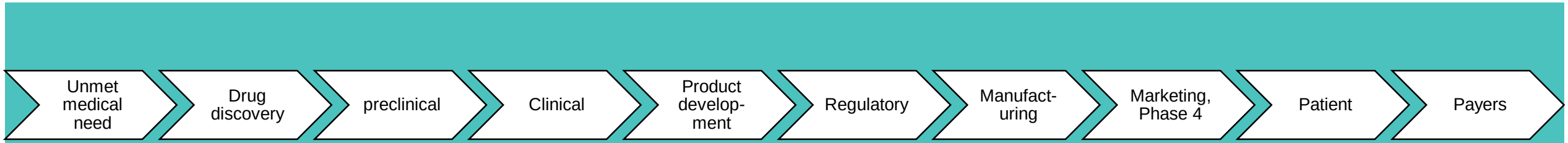
- There is substantial evidence of a USD 500 bio losses due to ineffective healthcare delivery
- Due to the reasons behind, patient centric drug products and therapeutic processes will most likely have a significant positive effect to reduce unnecessary spending



Source: IMS Institute for Healthcare Informatics (2012)

Challenge 6: The gap in transdisciplinary collaboration

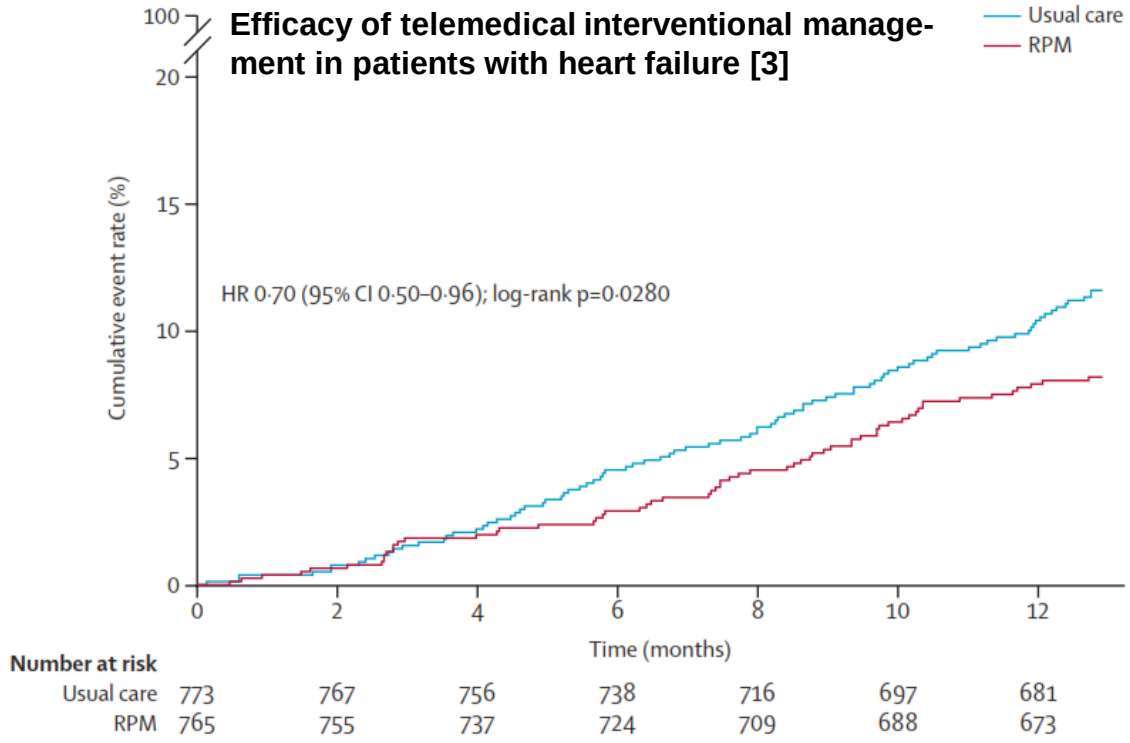
- Fragmentation in life sciences critically limits scientific progress, especially when fragmentation is increased by scientists open to influence only by peers with very similar views [1]
- Therapy development and healthcare provision are highly fragmented with a high degree of disconnect between disciplines (even within companies)
- A patient centric therapeutic development process involves all stakeholders and has to be build on shared expertise and collaboration on an aligned overall objective



1. Balietti et al PLoS ONE 10(3): e0118747 (2015)

Challenge 7: Exponential advancement in Science & Technology

- Companion or complementary diagnostics are becoming a mandatory part of drug development for complex diseases [1, 2]
- Clinical trials for digital healthcare provision increasingly demonstrate evidence of positive outcomes [3]
- Digital technologies are being tailored for special patient populations like older patients [4]
- Real World Evidence (RWE) & Real World Data (RWD) are playing an increasing role in health care decisions [5]



1. Sahlgren et al Adv. Healthcare Mater. 6, 1700258 (2017)
2. FDA (2018) Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product
3. Köhler et al. Lancet 2018; 392: 1047–57
4. Nikou et al Telemat Inform 53, 101315 (2020)
5. FDA (2017) Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Conclusion

Make the challenges opportunities

1. Including and addressing the patient perspective in the therapeutic process is paramount for achieving safety and effectiveness (instructions are not)
2. Create transparency of the interrelated sciences and expertise involved from discovery through to real world patients and clinical outcomes
3. Form the relevant transdisciplinary research & collaboration platforms/networks working towards improving effectiveness by considering patient views, needs and capabilities
4. Involve the targeted patients into the entire *therapeutic process* from the start
5. Develop methodologies to qualify and quantify patient centric therapeutic processes
6. Standardize/simplify & integrate emerging patient tailored technology into the therapeutic process
7. Build a comprehensive regulatory framework that encourage patient centric therapies
8. Create evidence for economics of patient centered therapeutics & healthcare provision

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We make tomorrow's drugs possible.

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