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Scenario building to uncover feasible solutions against publication bias

Results of Workshop 1

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UNCOVER adopts a participative approach to uncover feasible solutions against publication bias to arrive at a realistic future scenario for preventing publication bias. The focus is on stakeholder participation and involves a multi-step process. This report documents the scenario frames developed by stakeholders in Workshop 1.

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Scenario building to uncover feasible solutions against publication bias

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Summary

The UNCOVER project aims to identify and evaluate strategies to overcome non-publication of clinical studies that have been designed and executed as randomized controlled trials (RCTs). Work Package 5 takes a participative approach to uncover feasible solutions to arrive at a realistic scenario for preventing publication bias, focusing on stakeholder participation and involving a multi-step process.

One core aspect of this approach is scenario building. Scenario building is a methodological practice used in science, public policy, business and community settings when it is not easy to predict future trends, but action needs to be taken; and when it is important to engage different stakeholders, recognizing diversity yet building common ground in imagining possible futures. Scenarios are thus 'heuristic devices' to break away from conventional thinking, focus on mental models and strategic dialogue, and thinking systemically and holistically. The other core aspect is the transformative stance which entails to design a collaborative environment for stakeholders to engage fruitfully in identifying novel ways to overcome barriers in publication bias.

The goal is to convene a stakeholder group of actors covering the "whole system" of publication bias: taking different perspectives and expectations regarding the issue of publication bias associated with clinical trials into account. To facilitate the scenario building process two-day stakeholder workshops were conducted in June and September 2013 in Vienna. This Deliverable reports on the first Workshop taking place in June 2013. Experts and stakeholders were invited to collectively create multiple, alternative visions of the future ('scenarios'). Scenario frames were developed in interactive dialogue sessions and aim to address, firstly, goals and needs for change, secondly, key drivers and key activities to initiate change, and thirdly, challenges and opportunities for different stakeholders.

The first day was dedicated to analyzing the past as it helps to broaden participants' knowledge base for developing scenarios as possible pathways in achieving a desirable future. During the second day, participants examined a wider set of context factors and explored uncertainties based on the focal question, "How can we minimize publication bias to maximize patients' well-being - with a time horizon set for 2035?". They then composed a total of 19 short logical narratives of hypothetical future developments and identified metaphors and names for each scenario ('scenario frames').

1 Introduction

The UNCOVER project, funded by the European Union (Grant Number: 282574), aims to identify and evaluate strategies and ways to overcome non-publication of clinical studies that have been designed and executed as randomized controlled trials (RCTs). Work Package 5 takes a "participative approach to uncover feasible solutions against publication bias" to arrive at a realistic scenario for preventing publication bias, focusing on stakeholder participation and involving a multi-step process.

One core aspect of this approach is scenario building. Scenario building is a methodological practice used in science, public policy, business and community settings when it is not easy to predict future trends, but action needs to be taken; and when it is important to engage with the perspective of different stakeholders, recognize diversity yet build common ground in imagining possible futures. Scenarios are thought experiments ('heuristic devices') to break away from conventional thinking, focus on mental models and strategic dialogue, and thinking systemically and holistically.

The other core aspect is the transformative stance which entails to design a collaborative environment for stakeholders to engage in identifying novel ways to overcome barriers in publication bias.

The scenario process in UNCOVER thus aims at:

- Enabling different and potentially highly novel insights about how to address the needs around publication of clinical trials.
- Providing a mechanism for checking the robustness or responsiveness of new ideas and strategies in a range of possible futures - thus building confidence in future collaborations between various stakeholders.

The goal is thus to convene a stakeholder group of actors covering the "whole system" of publication bias: taking different perspectives and expectations surrounding the issue of publication bias associated with clinical trials into account. Stakeholders are invited based on different perspectives towards publication bias rather than simply on actor type. The interviews and desk research done by the UNCOVER team revealed a range of diverging positions on the issue which can be clustered into different 'perspectives'. For instance, publishing individual patient data seems to be an issue where clear pros and cons are to be found.

To facilitate the scenario building process two-day stakeholder workshops were conducted in June and September 2013 in Vienna.

This Deliverable summarizes the activities and output of the first workshop according to the UNCOVER Description of Work.

2 Objectives and methods

Experts and stakeholders were invited to collectively create multiple, alternative visions of the future ('scenarios'). Scenario frames were developed in interactive dialogue sessions and aim to address:

- Goals and needs for change
- Key drivers and key activities to initiate change
- Challenges and opportunities for different stakeholders

Day 1: Diagnosis of the current system

The first day was dedicated to analyzing the past as it helps to broaden participants' knowledge base for developing scenarios as possible pathways in achieving a desirable future. Stakeholders were presented key issues associated with publication bias and challenges of the future. The keys to "Responsible Research and Innovation"[1] were used to introduce state-of-the-art barriers and facilitators to reduce publication bias and STEEP factors (Socio-cultural, Technology-scientific, Economic, Environmental, and Policy) were used to identify trends and drivers.

Day 2: Projections of the future

During Day 2, participants examined a wider set of context factors and explored uncertainties based on the focal question, "How can we minimize publication bias to maximize patients' well-being - with a time horizon set for 2035?". They then composed a total of 19 short logical narratives of hypothetical future developments and identified metaphors and names for each scenario ('scenario frames').

[1] European Union (2012): Responsible research and innovation: Europe's ability to response to societal challenges. DG Research, Brussels.

3 First steps in scenario building

3.1 Diagnosis of the current system

To give the participants an overview of the current system and the current situation concerning the prevention or reduction of publication bias, measures designed and implemented to prevent and reduce publication bias were presented. These measures are:

- Changes in publication process
- Prospective registration of trials
- Open access policy
- Right to publication
- Research sponsors' guidelines
- Confirmatory large-scale trials

In a next step the main barriers, i.e. reasons why these measures often do not succeed in reducing publication bias, were presented to the participants. These inputs are based on the results of WP3 and should give the participants a broad overview of the current system.[2]

Subsequent to this presentation we started with a session where participants presented their perspectives, positions and values and started discussions. In two groups they identified the key issues related to publication bias from their point of view. Initial discussions revolved around the definition of "publication" which may refer to several dimensions: output, outcome (i.e. measure) and impact (i.e. effect, meaning) and could also mean "dissemination". The subsequent dialogue was characterized by consensus on the following issues: When it comes to patient (raw) data, participants voiced their concerns on the transparency in their use, barriers in accessing them and patient confidentiality. Moreover, reporting of methods is suboptimal. Non-publication may not only be caused by commercial interests of the pharmaceutical industry; it is equally academic research with its focus on the prestige and the impact factor of journal publications. Conflicts of interests, lack of awareness and failure to reach key players seem to remain problematic issues based on evidence of slow or lacking implementation of recommendations.

[2] Kien C, Van Noord M, Wagner-Luptacik P. Perspectives of stakeholders on publication bias in clinical trials. September 2013.Deliverable 3.4 of the UNCOVER FP7- funded project under contract number 282574.

3.2 Vision 2035 and the Focal Question for Scenario-Building

Acknowledging that innovation and transformation starts with a story about desired future, participants started to create their visions of a 'healthy' future in 2035. They were asked to incorporate key thoughts about the future of health care and health systems in this world as a consequence of reduced or abolished publication bias in their drawings. The participants analyzed the visions and concluded that

- a clean and green environment,
- collaboration,
- communication technology,
- work-life balance, and
- incremental change

are major characteristics of a 'healthy' future in 2035.

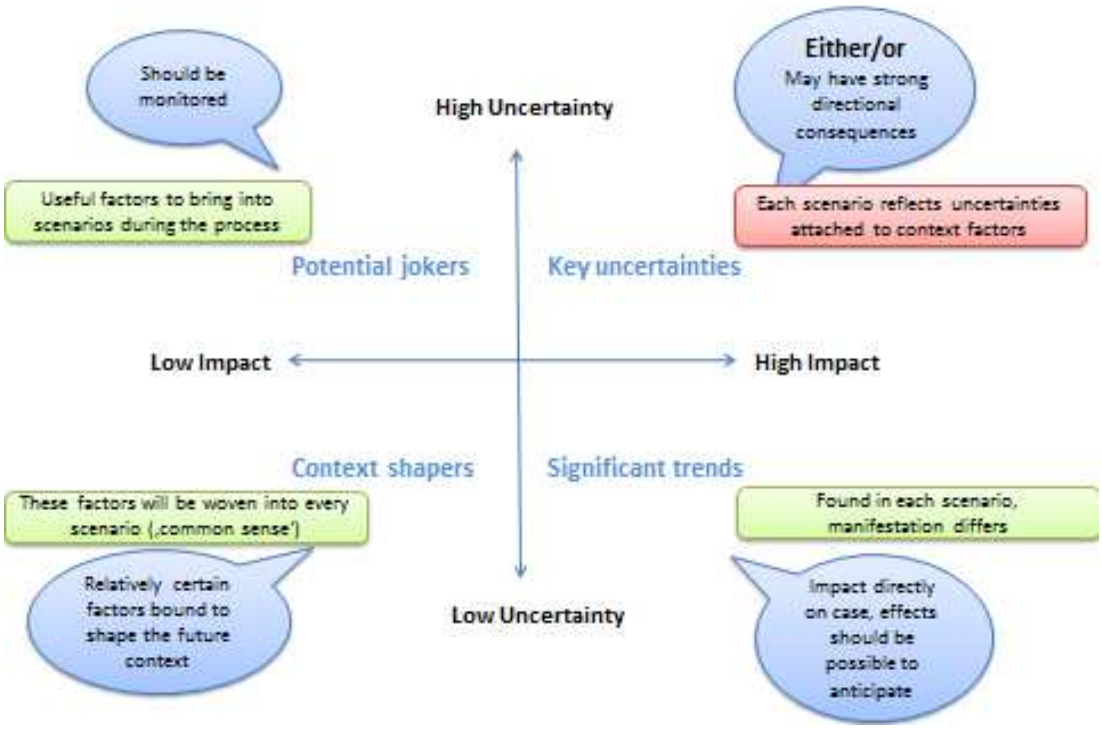
The visioning led to a focal question for building scenarios: „*How can we minimize publication bias to maximize patient well-being, with a time horizon 2035*?"

3.3 Contextual Trends and Drivers

As a next task participants had to assess major trends and drivers. As input they received a list of STEEP factors (see ANNEX 3). STEEP (Socio-cultural, Technology-scientific, Economic, Environmental, Policy) factors were assessed according to their likelihood of occurrence (*low uncertainty* | *high uncertainty*) and their likely impact (*high impact* | *low impact*).

Participants worked in two groups and organized STEEP factors into a grid (see Figure 1).

Figure 1: STEEP factor grid



Figures 2 and 3 below present the results of the two groups.

Figure 2: Uncertainty and impact of STEEP factors (group 1)

Figure 3: Uncertainty and impact of STEEP factors (group 2)

STEEP factors with critical uncertainty and impact were transformed into short and provoking projections for 2035. Participants had to think about each critical uncertainty as a question for which there are (at least) two possible outcome states (“projections”) so that the uncertainty can be ‘resolved’. The results of the projections were used for creating scenario frames.

4 Results: Scenario frames to prevent publication bias

Scenarios represent alternative but equally plausible pathways into the future. Each scenario will be presented in the form of a description of the contextual environment in which the scenario unfolds.

Participants searched for plausible connections and associations between key uncertainties. Factors may interconnect because of the impact of their influence on each other.

Participants composed a total of 19 short narratives (i.e. storylines of a few sentences) based on plausible connections and interdependencies among critical issues. These scenario frames are presented below.

4.1 "Completeness of Results and High Quality Reporting"

Lack of sufficient funding may result in incomplete results. Moreover, when intervention causes serious harms or when there is lack of sufficient subjects to recruit for the clinical study (because of infrequent affected persons in a certain population), the study may stop.

Completeness of results leads to use the research resources more efficiently. It will provide the answer for research questions and may find the probable gap of knowledge for the subject of study. The research will be reproducible when the results are complete. However, it needs to report in a high quality according to standardized guidelines. The critical appraisal would be possible with the complete results and it may lead to improving next studies in the subject. It also may provide some suggestions for further studies.

4.2 "Name and Shame" – A brave world

Pharmaceutical companies who do not agree to submit unpublished studies / do not allow publication of the complete trial data are penalized ("name and shame", no reimbursement of their products if alternatives are available) since the global regulatory system has been empowered by the EU parliament, after interventions from active patient groups and communities.

4.3 "Scientific Practice Influenced by Public Involvement and Implemented by Public and Private Collaboration"

An increase in public interest in use of available resources, both at the local and international level, forces a debate on public and private financing projects. Public and private sector share power and influence in society. Recent displays of power of influence from public uprisings (Arab Spring, Brazil, Turkey, China, India?) will lead to global push to adopting recommendations on good practice of science. This is directly influenced by new technologies and will have a direct effect on the use of resources and data.

4.4 "Backfire"

Increased transparency has led to open access to patient level data. Critical political (patient) groups fear loss of privacy and call on patients to refuse participation in clinical trials.

4.5 "Danger to Personalized Medicine"

Fear of the misuse of individual data leads to lack of patient participants in clinical trials. This leads to ensuring methods of data protection, making them less available for analysis, this could affect (slow down) the development of personalized treatments.

4.6 "Loss of Control"

More trials are funded from pharmaceutical companies because governments lack money. Companies invest a lot into public relations and good image, but they also remain in-transparent. They only communicate to the public what is in their interest – hardly any official control because too little money – people are uncritical.

Patients are awakening and there is more community involvement, but they are not well informed. Little money spent on education, not validated information influences their opinion. They believe what companies tell them, they are manipulated and engage for the "wrong aims" (e.g., block innovations).

Publication bias lives on; people are uncritical and even support it.

4.7 "Agenda 2035"

A global regulatory system has been implemented – pharmaceutical companies are given incentives for submitting unpublished data (e.g., an additional year of market exclusivity). A summary of the results/outcome of every trial registered in a centralized world-wide register has to be published. The original (de-personalized) data are deposited in an associated register and available (under certain conditions) to researchers.

4.8 "Rx Gold Standards"

Patients are better informed about their health and communities are actively involved in developing healthy infrastructures as a result of political and ecological awakening. Doctors will now only prescribe medications with a "WHO Seal of Approval". These medications have been heavily regulated in their development, following a transparent process that included global trial registration, open access publishing, etc.

4.9 "Our Own Worst Enemy"

Societies have realized that "we are our own worst enemy" and money previously spent on defense is now spent on healthcare. Government spending on trials has increased and created stiff competition for the pharmaceutical industry, which has led to increased transparency, reproducible, and more objective results.

4.10 "Scientific Shift"

In the future there are no health stigmas and we are constantly uploading data into global data sets. The data is constantly being aggregated and providing feedback about the health status of society. There is, therefore, a shift from scientific research as we know it, moving away from drug research into DNA, molecular, personalized investigation. Society and the public as a whole, both at the collective and the personal level, are key players and stakeholders in scientific research, which forces the implementation of new measures that, for instance, protect personal data, etc.

4.11 "We Can See Clearly Now…"

Drug regulators open their databases and/or give public access to study reports.

- Journals publish commentaries and syntheses (corporate social responsibility!)

- Leads to development of similar systems for non-drug studies

4.12 "Mandatory HIA for Public Regulator"

This future is about "increase awareness leads to more engagement and sustainability". Health Impact Assessment (HIA) for all regulatory instruments (laws, directives) becomes obligatory within European Union. National policies have to do the same:

- Defining population at risk
- Defining possible impacts
- Proposing methods to assess them
- Excluding all necessary research and/or data-collection
- Open documentation and reporting of all findings
- Publish findings for stakeholders
- Discuss results with lawmakers and representatives of people supposed to be at risk
- Decision-makers demanding public structures of research, data-mining, and reviewing for all political levels of decision-making
- Civil society fighting for more and better democratic bodies to control and guide the decision-making process

4.13 "Funders Take Over"

Funders already set aside funds for publication: money for publishing results is already often part of grants. These costs could include writing fees or article processing charges (APCs) for open access (OA) journals. APCs should decrease over time as new publishing models develop. Funders could also redirect the money to pay for subscription-based journals (e.g., pay for OA journals). In any case, funders could apply penalties to researchers who do not publish (e.g., they do not get the final funding or will not get any funding in the future).

4.14 "'Big Brother' Trial"

A principal investigator sets up a webpage where the protocol and all the details of the study are available. As the trial processes more and more results (aggregated data) are automatically produced due to a pre-specified analyze code.

This will catch the attention of the public and they will be talking about it and increase thus participation in trials. They could even spot the fabrication of data.

4.15 "Citizens Uprising"

Active citizenship will lead to demands and riots in front of funders, universities, hospitals. The "All Trials" campaign receives 80 million supporters which leads to demands for pharmaceutical companies and funders to have reports of all ongoing and unpublished trials. The public eventually become shareholders.

4.16 "Death of the Impact Factor"

Institutions create effective incentives for researchers to post their results on public databases (including commercial studies)

- Growth of databases
- Change in journal role

The impact factor is no longer important.

4.17 "Journals 'R' Us"

Changes in research funding → funders publish their own studies → funders might produce own journals → standardization of publishing templates → journal refocus on commenting publications → (possible resistance from journals) → new metrics developed for research prestige and authorship

4.18 "Give Us the Data!"

Drug licenses only given if companies allow independent organizations to curate data/analyze it

- All data/results in public databases
- Pre-defined +/- public analysis

4.19 "2084"

Regulatory body (linked to regional ethic committees) regulates

Results posting → European Union results database (standard template; multiple languages).

Link between registration at time of approval and results posting → consistent/truthful reporting non-posting = seen as unethical.

5 Outlook on Workshop 2: Scenario Enrichment

The aim of the second UNCOVER scenario workshop will be to discover what can and should be done (i.e. measures) by whom (i.e. stakeholders) to prevent publication bias in the future. Using the storylines developed in the first workshop as 'seeds' for change, stakeholders will further develop transformative scenarios with relevant goals, stakeholders and measures - framed by 'dominant' institutional arrangements. Participants will work out what success might look like for each scenario by taking advantage of levers and opportunities, overcoming or weakening the impact of barriers and identifying responsibilities and accountabilities. For each scenario, insights will be generated about collaborative measures that might be pursued between stakeholders if a specific scenario 'world' became dominant and conclusions drawn about what each stakeholder will and can contribute for change ('readiness' and 'influence'). After checking for plausibility and robustness, the most viable scenario will be selected for a better understanding of how the timing and sequence of events may influence the possibilities of turning ideas and goals into practice.

ANNEX 1: Agenda Workshop 1

Diagnosis of the current system, future visions (Day 1)

08:30 – 09:00	Welcome & Coffee
09:00 – 09:15	The UNCOVER project – aims & insights
	Project coordinator M. Kienegger, AIT
09:15 – 09:30	Introduction to the Workshop
	Process Facilitator P. Wagner-Luptacik, AIT
09:30 – 09:45	Check-In by participants
10:00 – 11:00	**Session 1: Analysis of the current system**
	Presentations by B. Nußbaumer and M. Van Noord, DUK
11:00 – 11:15	*Coffee Break*
11:15 – 12:45	**Session 2: Exploring divergent perspectives, positions, values**
13:00 – 14:00	*Lunch Break*
14:00 – 15:45	**Session 3: Vision 2035 – Exploring the focal question**
	Creative activity
15:45 – 16:00	*Coffee Break*
16:00 – 17:30	***Session 4: Identifying trends and drivers***
19:00	*Dinner*

In search for therapy: Scenarios as future pathways (Day 2)

09:00 – 09:15	Check-in
09:15 – 10:45	***Session 1: Assessing trends and drivers***
10:45 – 11:00	Coffee Break
11:00 – 13:00	***Session 2: Creating scenario frames (part 1)***
13:00 – 13:30	Lunch break
13:30 – 15:30	***Session 3: Creating scenario frames (part 2)***
15:30 – 16:00	Outlook on Workshop 2, Farewell

ANNEX 2: Workshop Participants

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ANNEX 3: STEEP Factors

SOCIAL / CULTURAL FACTORS

GLOBAL TRENDS

- **Social inequalities** - relational processes in society that have the effect of limiting or harming a group's social status, social class, and social circle
- **Change in the demographic population structure**
    - increased mobility of members of the society
    - diverse migration patterns (immigration and emigration)
    - movement from the rural to urban places (urbanization)
    - aging population due to higher life expectancy in the Western countries
- **Work force development** – growth, decline
- **Lifelong learning –** access to education (basic, continuous)
- **Power of women** - women will exert a more prominent power in society ("feminization" of society and economy)
- **Global citizenship**
- **Active citizenship** – health and rights of citizens, particularly as patients
- **Attitudes towards solidarity** - intergenerational, ethnic, regional and socio-economic solidarity
- **Population structure** - distribution of various gen/gender groups in a population

HEALTH-RELATED TRENDS

- **Health culture**: social attitudes, practices and habits towards desirability of healthy living and active lifestyles
- **Incidence of Chronic Diseases**: population mortality and work days lost to non-communicable diseases
- **Community Involvement**: dynamism of civil society and involvement of local communities in health provision
- **"Better informed consumers"**: consumers decide for themselves what risks they want to take

- **Patient Initiatives**: patients provide their own data for studying raw diseases
- **Rise in obesity**

ECONOMIC / BUSINESS FACTORS

GLOBAL TRENDS

- **General State of the Economy**
  - GDP growth per annum differs widely on the national and global level.
- **Resource availability**
  - lack of equality of access resources - water, food, energy, land, minerals
- **Income inequality**
  - income (including social transfers) varies greatly between different social communities
  - percentage of population under the poverty line increases steadily
- **Shifting centers of economic activity**: from developed countries to BRIC-States (Brazil, Russia, India, China) for production and new products as well as consumers
- **Waves of mergers and acquisition**
- **Foreign direct investments**
- **Virtual economy**
- **Work force growth/decline**
  - higher rates of entrepreneurs in the workforce

HEALTH-RELATED TRENDS

- **Rising costs for the health care system**
  - As a consequence of the changing social structures and changes in demographics as well as the implementation of costly technological advances health care costs are expected to increase considerably.
- **Different set-up of companies in the health care sector**:
  - large multinationals
  - middle-sized multinationals

  - small companies developing new drugs with the aim of contributing products into the pipelines of the multinationals
  - small companies providing analytical and other services to multinational companies

- **Changing image of pharmaceutical industry**: the image of the pharmaceutical industry is becoming increasingly negative.
- **Surging information wave and related safety & security issues**
  - technical developments allow for the generation, processing and storage of large data sets ('big data'), e.g. derived from the human genome ('personalized medicine')
  - the use of 'big data' may result in a loss of control of the individual and lack and raise privacy issues ('individualism vs. collectivism').
- **Open access** to scientific findings and existing knowledge is widely demanded.

POLITICAL / LEGAL FACTORS

GLOBAL TRENDS

- **Origin of governance** and overall **shift of the level of governance**
  - At which level will policy for the society be set in the future - supranational, national, local?
- **Increasingly global regulatory system**
  - stronger/weaker ties between member states of the European Union
- **Influences over lifestyles**
  - the ability and the willingness of the state and organizational bodies to directly influence the lives of the population is expected to increase.
- **Market regulations**
  - regulation regarding marketing new products will become stricter, thereby hampering marketing new products
- **Bureaucracy**
- **Transparency**
- **Privacy**

HEALTH-RELATED TRENDS

- **Health care decisions** will rely on improved collection and transparency of health data
- **Healthcare spending** will continue to rise
- **Changes in health care delivery**: more evidence-based and information building on increasingly universal electronic health records
- **Health insurance** – public vs. private
- **Higher dependence ratio**: concern about the financing of the retirement system and the health care system
- **Shift in focus**: currently the focus of health care is shifting from cure to prevention
- **Patient's responsibility**: Strengthening the patient's responsibility for his/her owns health
- **Conflicts**: mortality and serious injury due to violence

TECHNOLOGICAL / SCIENTIFIC FACTORS

GLOBAL TRENDS

- **Access to information**
    - Increasing availability and use of digital data within the population
    - changes in attitudes towards privacy and sharing of data
- **Technology optimism** ('Social life in a technological world').
- **R&D convergence** ("neuro, bio, nano, cogno")
- **Increase in investments into bioscience and biotechnology** by the industry/by the public funders
- **Students taking science, engineering and technology subjects:** it is expected that the overall number of students in science and engineering will increase.

HEALTH-RELATED TRENDS

- **Translation of research findings into clinical practice**
    - The capability and the infrastructure for clinical trials and "translational" research need to change.
- **Personalized medicine**

- Due to enhanced methods, decreasing costs of genetic screening, and enhancing diagnostic abilities, a paradigm shift in the health care system towards personalized medicine is expected.
- Drugs are more and more tailored to the individual genetic profile of a patient; drug delivery will be more targeted through molecular recognition ('pharmacogenomics').
- Due to the advances in personalized medicine, medicine will become more predictive, preventive, personalized and participatory ('P4 Medicine').

- **Drug development**
  - Hardly any changes in conventional drug development
  - innovations in new development of drugs
  - larger samples of patients and larger timescales needed to show additional benefit
  - Computational (or "in-silico") drug discovery and testing will increase
- **RTD innovations**
  - R&D findings and technology innovations (e.g. nanotechnology, biotechnology, synthetic biology, computational chemistry, Bio-interfaces, hospital robotics, artificial muscles and tissue) have a profound impact in the health care system, particularly for disease management
    - Interdisciplinary approaches (collaborations between different disciplines)
    - Transdisciplinary approaches (collaborations across industry, academia and clinical medicine, campus industry partnerships)
  - Public sector organizations involved in basic discovery and in offering supporting services to the commercial sector
  - Better health diagnostics
  - Usage of computers and software to design new drugs

ENVIRONMENTAL FACTORS

GLOBAL TRENDS

- **Climate Change**
  - Local exposure to extreme weather and changing local resource availability

  - Weather-related mortality and new diseases such as malaria in Europe

- **Carbon pollution**
- **Pollution and toxicity**
  - Effect of exposure to chemical, biological and/or radiation agents (occupational and residential) on human beings.
- **Growing demand for energy**
- **Limited resources**
  - Food shortage, increasing scarcity and unequal distribution of water in various regions of the world.

HEALTH-RELATED TRENDS

- **Climate Change**: weather-related mortality and new diseases such as malaria in Europe will increase.
- **Incidence Infectious Disease**: population mortality and work days lost to communicable diseases, as well as antibiotic resistance is expected to increase.
- **Population Sanitation**: access to sanitary tools will have an impact on the public health as well as the ability of preventing exposure to waste, and ensuring water and food quality.

Sources:

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