BETTER POLICIES FOR BETTER LIVES

Science and Societal Challenges: Moving Ahead

Health-related work building on "Meeting Global Challenges through Better Governance: International Co-operation in Science, Technology and Innovation"

Science Diplomacy in Action

Governance for international science co-operation: the example of health research

Paris, 11-12th February, 2013

Ken Guy - OECD
Head, Science and Technology Policy Division

Tackling Global Challenges

- Societies are facing challenges of unprecedented **magnitude**
- Most of these challenges are of a **truly global** nature crossing national borders and affecting a wide range of actors
- Yet in most cases, single governments cannot provide effective solutions to challenges such as…

  - **climate change**
  - **energy**
  - **global health**
  - **agriculture and food security**

What Can Governments Do?

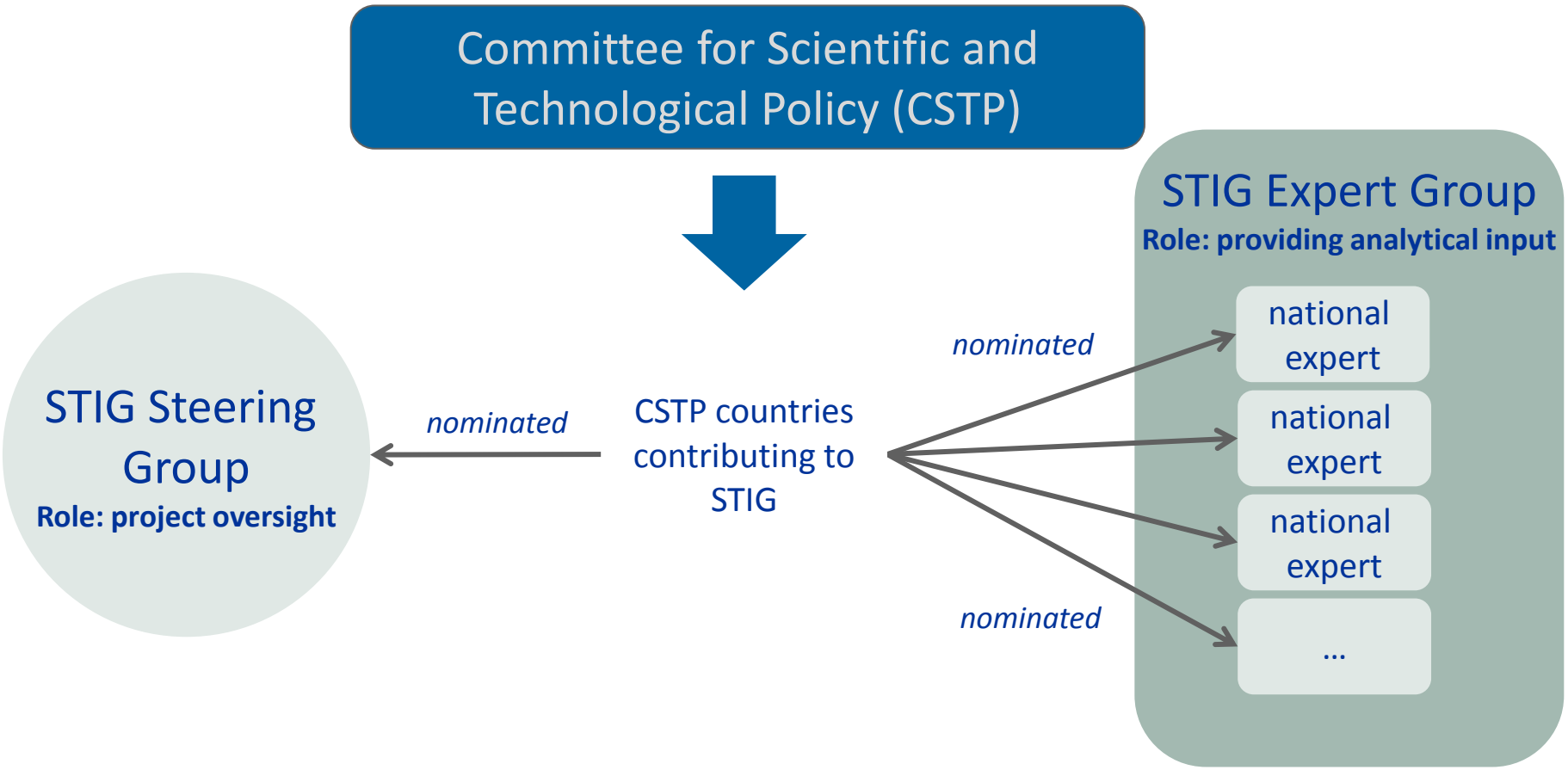
Global challenges require co-operation on a global scale to **build capacity** in science, technology and innovation (STI) at both **national** and **international levels**

- ***How can international co-operation in STI be scaled up and it's scope broadened?***
- ***How do different modes of governance of international co-operation in STI function and which modes lead to effective an efficient collaboration?***

The OECD, through its Committee for Scientific and Technological Policy (CSTP), established the:

Steering Group on Governance of International Co-operation on Science, Technology and Innovation for Global Challenges (STIG)

Organisation of STIG Project



Focus

- Concentrated on **the governance issue** of international co-operation in STI, including the strengths and weaknesses

- **Involved a range of policy makers**, including those from emerging & developing countries, with the aim to:
  - Share best practices
  - Facilitate collective learning
  - Build expertise and networks among participating countries, as well as with the private sector, NPOs and other stakeholders

Case Studies

- The Consultative Group on International Agricultural Research (CGIAR)
- Bill and Melinda Gates Foundation
- The Group on Earth Observations (GEO)
- The International Atomic Energy (IAEA)
- The Inter-American Institute for Global Change Research (IAI)
- The International Energy Agency (IEA) Implementing Agreements
- Joint Programming Initiative (JPI) – Agriculture, Food Security and Climate Change (FACCE)
- …and 2 mini case studies on The Global Carbon Capture and Storage Institute and The International Arabidopsis Genome Research Project

Results

www.oecd.org/STI/Stpolicy/governance

Meeting Global Challenges through Better Governance

INTERNATIONAL CO-OPERATION IN SCIENCE, TECHNOLOGY AND INNOVATION

Contents

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Meeting Global Challenges through Better Governance INTERNATIONAL CO-OPERATION IN SCIENCE, TECHNOLOGY AND INNOVATION

Meeting Global Challenges through Better Governance

INTERNATIONAL CO-OPERATION IN SCIENCE, TECHNOLOGY AND INNOVATION

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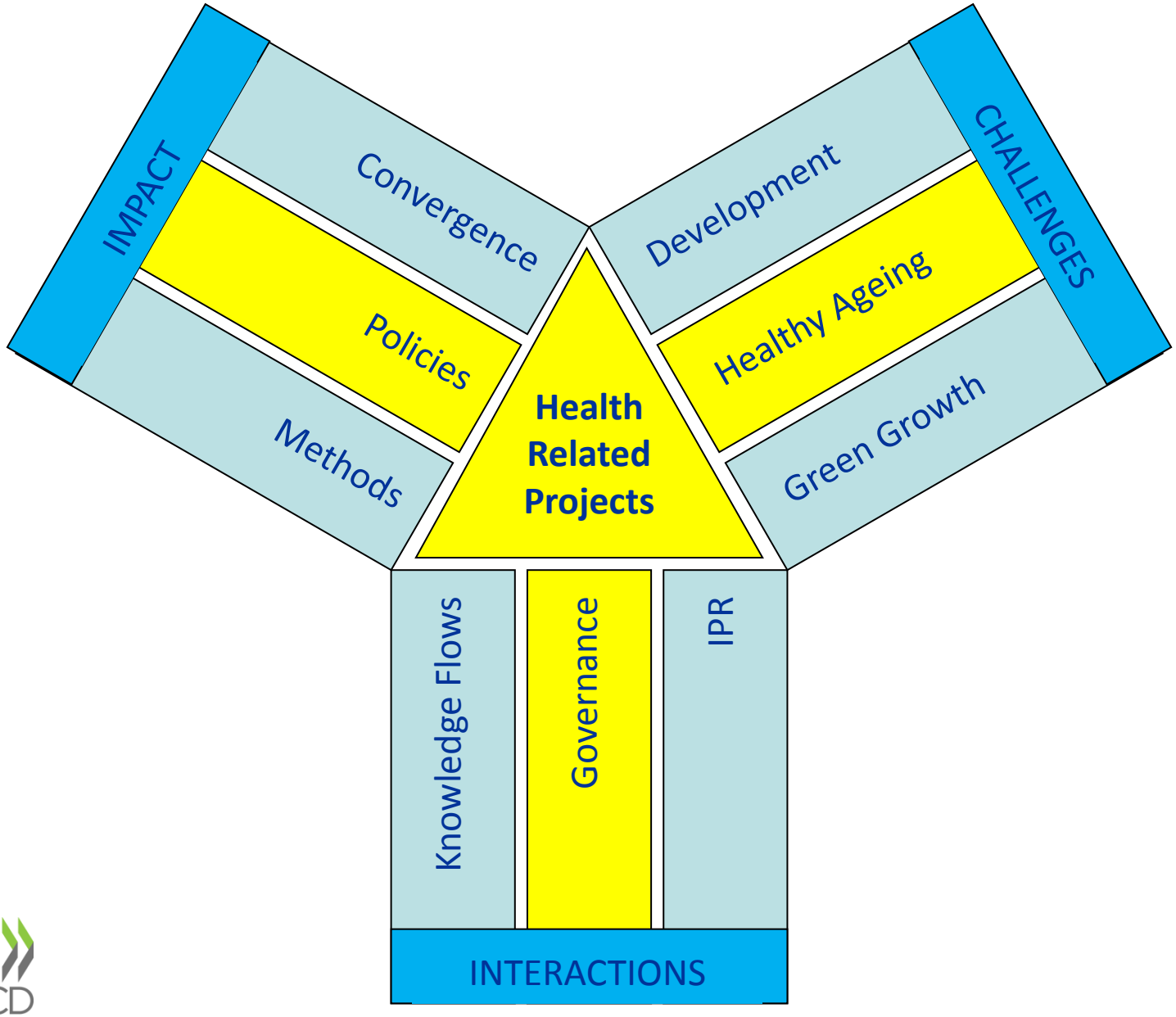
Future Work

- **The topics tackled in the STIG project are being now being mainstreamed and further developed within the three priority themes of the OECD's CSTP 2013-2014 Programme of Work and Budget (PWB):**

  - Impact of Science and Technology on Economic Growth and Social Welfare
  - Enhancing Science, Technology and Innovation (STI) Interactions and International Cooperation
  - Fostering STI to Address Global Challenges

Health-Related Projects



Health and Healthy Ageing

Recent advances in science and technology, promise new understandings of disease and responses to disease, with the potential to transform innovation in health care and biomedicine

- The pursuit of public health is an important economic, scientific and social endeavour for all countries
- Governments recognise the links between health, economic productivity and national prosperity (contribution to the bioeconomy)
- Globalisation has created additional public health challenges:
  - Changing diets
  - Greater mobility
- Consequently, many governments now support policies and programmes that address global as well as national public health challenges

Building on Existing Work

- OECD Council Recommendation on Clinical Trials (Dec 2012)
- Public Health in an Age of Genomics (due 2013)
- Innovative Governance in Biomedicine and Health Technology (due 2013)
- Emerging Trends in Biomedicine and Health Technology Innovation: Addressing the Global Challenge of Alzheimer's Disease (due 2013)

OECD Council Recommendation on the Governance of Clinical Trials

RECOMMENDS *that Members adapt their national regulations and procedures to incorporate a risk-based methodology for the oversight and management of clinical trials, taking into account the principles set out in the Annex to the Recommendation*

Rationale:

- Clinical trials increasingly involve international researchers and collaborations (faster patient recruitment / greater capacity to address rare, neglected and complex diseases/trial results more rapidly available/results more generally applicable etc.)

But

- Differences between national requirements and interpretation of existing regulations and other processes have led to high administrative complexity
- Identical requirements for all trials independent of the risks involved penalises academic trials, which often use well-known established treatments/drugs

Many well-conceived clinical trials addressing important health problems are either not conducted or delayed to such an extent that their impact is dramatically reduced

Two Major Objectives

1. **Harmonise regulatory frameworks to facilitate international collaboration /multinational clinical trials:**

   In the EU, nearly 25% of all clinical trials applied for are now multinational clinical trials, i.e. clinical trials intended to be performed in at least two Member States. These trials involve approximately two thirds of all subjects enrolled in a clinical trial, so mono-national clinical trials are now largely limited to small studies with low recruitment targets.

2. **Streamline procedures for low-risk trials while enhancing the protection of participants:**

   The number of clinical trials, particularly those initiated by academic investigators for non-commercial purposes, has been falling in recent years in some regions (in the EU, the total number of applications for clinical trials fell by 25 % from 2007 to 2011).

The Recommendation focuses on clinical trials on medicinal products. It is primarily driven by the need to facilitate multinational trials undertaken by academic groups, but Members may wish to extend its implementation to all clinical trials.

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An International Collaborative Process

October 2009, the Delegations of Germany and Spain introduced a proposal for a new activity to the OECD Global Science Forum on "Clinical Research"

April 2010, creation of an Expert Group to "Facilitate International Cooperation in Non-Commercial Clinical Trials" (23 countries and 10 international organisations represented)

October 2010, the Expert Group produces its final report, which includes a series of policy recommendations, including that of an OECD Council Recommendation on the governance of clinical trials

September 2012, a draft Recommendation prepared by a second Expert Group (58 experts from 24 countries and international institutions), co-chaired by France, Japan and the USA, is submitted to the GSF, and then to the CSTP in October 2012

December 2012, the Council of the OECD adopts the Recommendation on the governance of clinical trials

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Public Health in an Age of Genomics

How do new developments in genomics influence the way that public health, both national and global, is understood by different countries?

- How do countries go about setting their priorities and delivering on them?
- What policies are in place to enable the development and translation of genomics for public health benefit?
- To what extent are they focused on domestic public health, and to what extent on global health?
- How successful have such policies been in delivering public health, either in-country or globally?

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Public Health in an Age of Genomics

- **The use of genomics for infectious disease control is already yielding significant public health benefits**, both in terms of the ability to diagnose and track the movement of infectious disease outbreaks and in terms of the ability to enhance and accelerate the production of effective vaccines
- **There are significant differences of priority between countries**. Higher income countries are motivated primarily by the promise of stratified medicine, while lower and middle income countries concentrate more heavily on the control of infectious diseases
- **International collaboration is essential if the full potential of genomics for infectious disease control both nationally and globally is to be realised**. **By contrast the development of stratified medicine tends to be seen as primarily a national issue**, with international initiatives in this area directed towards fostering an appropriate regulatory and economic environment supportive of national innovation
- Consequently, **richer countries are less dependent on, and less inclined to seek, international collaboration than low and middle income countries**
- **The benefits of stratified medicine are likely to be realised within local genetic populations and will be felt chiefly on a national or regional basis**. By contrast, infectious diseases pose potentially global threats, and **the benefits of genomics for infectious disease control may therefore be felt on a global as well as a local scale**

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Alzheimer's Disease (AD)

- 35 million people suffering from AD, rising to 115 million by 2050
- Just one of many devastating neurodegenerative diseases (NDG)
- Occurs in all parts of the globe, rich and poor
- Significant, and rising, direct and indirect costs in healthcare and wider society and the economy

- No cure
- No effective (early)diagnosis
- No real treatments
- No vaccine

AD and Governance

- Governments are making difficult decisions about what to fund:
  - Research and Development e.g. Biomarkers
  - Infrastructure e.g. R&D, linked databases
  - Translation and clinical trials
  - Regulation and legislation
  - Delivery and diffusion of new options
  - Direct care
- Examples of good practice and new models of governance are needed:
  - Longitudinal studies to clarify and predict
  - Data mining to feed into health innovation
  - Public-private partnerships, multi-stakeholder collaborations
  - Research and research translation – effective supports

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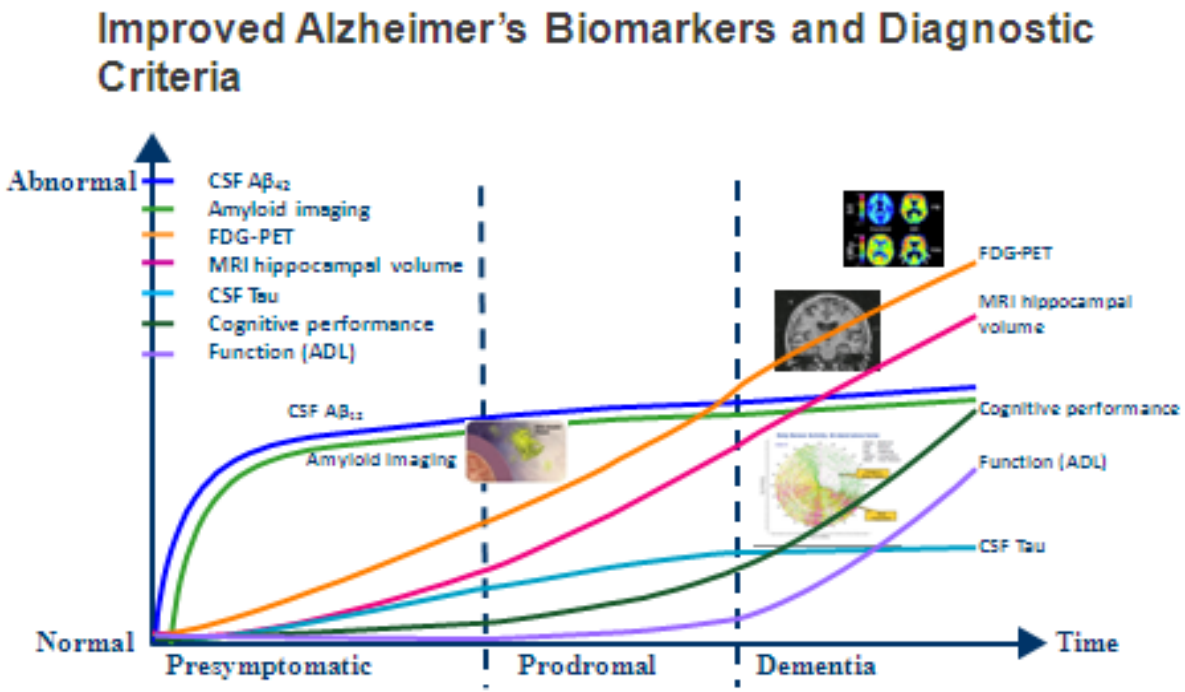
AD and Innovation

- Accelerating innovation on new biomarkers and diagnostic criteria
  - Even a modest delay of five years in the onset of brain disability through improved diagnostics can reduce the cost and prevalence of AD by half.



Modified from Aisen PS *Alzheimers Dement.* 2010

Main Aims of the Project

- Collect and analyse available information on the economic and social impacts of AD
- Consider how to accelerate knowledge mobilisation, translation and valuation- and the need for new governance frameworks
- Characterise the types of big data emerging for AD and the policies needed to address the challenges in trans-border data flows and database linkages
- Prepare the groundwork for an open-access comprehensive multi-national database
- The long-term goal of the project is to set up an international coordinating mechanism to accelerate innovation to address the global challenge of AD

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AD as proxy for NDGs

The *scope* and *scale* of the challenge represented by Alzheimer's disease may provide the impetus for much needed new thinking about policies to enable biomedicine and heath innovation across the entire innovation cycle: from research and development to commercialisation, regulation, delivery and diffusion.

HUGO Workshop on Healthy Ageing

Integrating Omics and Policy for Grand Challenges: Healthy Ageing

OECD/HUGO Session at the Joint Conference of the Human Genome Meeting 2013 / 21st International Congress of Genetics

Saturday 13 April 2013 from 10h00 to 12h30, SINGAPORE

- ***Speakers:*** Diana Bowman, University of Michigan/University of Twente; Michael Hodin, Global Coalition on Ageing and High Lantern Group; Tom Kirkwood CBE, Director of the Institute for Ageing and Health, Newcastle University; Jenni Nordborg, Vinnova; Teo Yik Ying, National University Singapore; Margaret Wright, Queensland Institute of Medical Research; Gerardo Jimenez-Sanchez, Harvard School of Public Health, Chair of WPB
- ***Topics:*** Genetics of healthy ageing; Convergence of technologies – Informatics for Biomedicine; Regulatory perspective; Policy for Biotechnology Innovation in Healthy Ageing; Older Australian Twins Study (OATS) & other research; and The need for global action on ageing

http://www.hgm2013-icg.org/scientific_programme.html

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Thank You

For further information please contact:

Ken Guy

Organisation for Economic Co-operation and Development (OECD)

ken.guy@oecd.org