

# Initiative overview

EUROPEAN HEALTHCARE INNOVATION LEADERSHIP NETWORK  
PILOTS OF MULTI-STAKEHOLDER CONSULTATIONS IN DRUG DEVELOPMENT

NOVEMBER 2011

## Creating a more sustainable model for innovation in an era of scarce resources

The European Healthcare Innovation Leadership Network (“the Network”) was established by Tapestry Networks in 2006. AstraZeneca, GlaxoSmithKline, and Johnson & Johnson fund this independently-led initiative, with Bristol Myers Squibb recently joining in 2011. The Network brings together a premier group of healthcare leaders from EU Member States who are committed to improving patient health outcomes and enhancing the climate for innovation, while acknowledging pressures to control healthcare costs (*Please see attached list of Network members.*)

Network members are motivated by a confluence of factors: we are entering a “new world” in which generics are more readily available and represent an economically attractive alternative to innovative medicines. Meanwhile, R&D is “in a period of low productivity” and health systems face increasing economic pressures. While progress on chronic diseases and a scarcity of resources have raised the bar for assessing and demonstrating the value of new medicines, continuing to address unmet medical needs and improve patient outcomes remains the ultimate goal for all healthcare institutions.

To advance these objectives, the Network has supported an initiative to develop and test shared value frameworks for evaluating new medicines. The first phase of this effort brought together expert, multi-stakeholder working groups focused initially on breast cancer and type 2 diabetes. In the current phase, healthcare institutions from across Europe are applying these frameworks through pilots of multi-stakeholder consultations in drug development (“the pilots”). Additionally, the Network is exploring new topic areas that call for a multi-stakeholder approach to improve healthcare outcomes.

## Shared value frameworks for evaluating new medicines

Network members recognised that moving from a general consideration of how to define value in new medicines to concrete outcomes required a disease-specific focus. Network members and Tapestry Networks identified two initial therapeutic areas – type 2 diabetes and breast cancer – chosen for their high unmet needs and impact on healthcare systems. In 2009, Tapestry Networks convened the type 2 diabetes and breast cancer Working Groups, bringing together leading medical experts, regulators, payers, reimbursement authorities, patients and industry representatives from across Europe (*Please see attached list of Working Group participants.*)

Working together over the course of 2009, Working Group participants established a shared value framework – an agreed set of attributes, therapeutic endpoints and economic inputs – for evaluating new medicines within specific therapeutic areas. Participants also identified a number of difficulties in the drug development process that limit the ability of health systems to deliver the right medicines to the right patients at the right time. These difficulties include the high cost of bringing innovative new medicines to market, the limited additional benefit over existing treatments that many new medicines provide, challenges in providing newly developed medicines that do promise significant improvement in health outcomes to patients in a timely manner, and identifying the appropriate patient populations for delivery of these medicines.

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Participants recommended the creation of a process for multi-stakeholder consultations in drug development to help address these challenges. The process is intended to improve clarity and alignment among diverse stakeholders regarding what constitutes a medicine's value and how companies should demonstrate that value, thereby informing the design of clinical development programmes.

At the Network's January 2010 meeting, members and guests affirmed the Working Groups' recommendations and, with the support of Tapestry Networks, catalysed the launch of the pilots. Network members recognised that no single stakeholder group acting alone can successfully accomplish this goal. Thus, the call went out in support of the pilots, an experimental process *"to demonstrate how you might design something different where all stakeholders and patients would benefit."*

## Pilots of multi-stakeholder consultations in drug development

On 14–15 July 2010, leaders of healthcare institutions representing five Member States and the European Union (EU) convened in London to launch a new pilot process testing multi-stakeholder consultations in drug development. Participating stakeholders and Tapestry Networks jointly designed this process, with guidance from existing early advice processes and input from key European healthcare leaders.

Between September, 2010 and February, 2011, healthcare leaders and Tapestry Networks tested this process by completing the first set of three pilot consultations, each involving a medicine being developed by one of the initiative's sponsors. The first two consultations involved a medicine for type 2 diabetes being developed by AstraZeneca and GlaxoSmithKline, respectively. The third concerned a breast cancer medicine under development by Johnson & Johnson / Janssen.

Participating institutions included the European Medicines Agency (EMA), health technology assessment (HTA) agencies from France, Italy, the Netherlands, Sweden and the United Kingdom, as well as a German academic HTA Centre and regional payers from the Netherlands, Sweden and the UK. Medical experts and patient advocates completed the consultation groups *(Please see attached list of institutions contributing to the pilots)*.

Participants believe that the drug development process is more likely to deliver medicines and supporting evidence that meets the needs of various stakeholders if they engage in an open dialogue with each other. Accordingly, the initial pilots have provided a valuable forum for drug developers to seek an integrated perspective on the prospective value of a medicine under development along with how best to demonstrate that value. The pilots also present a unique opportunity to learn about the benefits and limitations of a multi-constituent approach to informing drug development.

Following the conclusion of the first set of pilots, Tapestry Networks compiled and published a set of findings reflecting participants' experience and its implications for future multi-stakeholder consultation initiatives. Participants and drug developers continue to show strong enthusiasm for testing and refining the pilot process and have launched a second set of pilot consultations, with

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one consultation completed on 1 July 2011 and three additional consultations planned for December 2011 and 2012. New participants for this second set of pilots include representatives from HTA and regulatory bodies in Germany, HTA and payer bodies in Spain and representatives of the European Commission.

## Future Network efforts to improve health outcomes

Network members believe the pilots are but one means of unlocking the potential for improving health outcomes in Europe. To this end, the Network will explore additional areas in which a multi-stakeholder approach can create benefits for a health system, including exploring the impact of emerging models of pricing and access on patients, cost control, and value-added innovation.

## About Tapestry Networks

Our mission is to advance society's ability to govern and lead by developing new ways for people to work together across the borders of sector, geography and constituency. These initiatives – which we regard as networks because of the way they are constructed and function – typically address complex issues where public interest and private sector innovation need to be aligned. The participants in these networks are respected leaders from the public and private sector as well as civil society. Tapestry's networks enable them to lead beyond the borders of their organizations, sectors, and countries to achieve objectives of both public and private interest.

Tapestry, at its core and from its inception in 2003, is built on several basic beliefs. We believe that relatively small groups of well-positioned leaders, seeking a goal that transcends the interests of any one constituency, can make progress toward that goal (no matter how elusive it has been previously) through the network-based approaches that Tapestry designs and leads. We believe that value – both societal and economic – is often destroyed or constrained because many of the mechanisms that connect business, government and society were developed for an environment without today's level of complexity, interconnectedness and interdependence. Leaders today are confronted not with neatly defined problems but complicated and inter-related “messes.” In this environment, we believe that progress requires that our network participants think big, start small with thoughtful experiments and build momentum along the journey to a better future.

Tapestry Networks has adopted principles and guidelines for public-private networks that support the legal and ethical responsibilities of its sponsors and members. *(Please see attached document specifying our principles and guidelines.)* Thus, our networks provide an informed and safe environment for all members to find common ground and generate uncommon insights that have the potential to break stalemates and create enormous value. Through sustained conversations and actions aimed at reaching a super-ordinate goal, members build trust in each other, gain confidence that the goal can be reached and find the courage to develop and test new strategies.

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## Network Members and Alumni

### Member States

#### Czech Republic

- **Pavel Hroboň\*** | Former Deputy Minister | Ministry of Health

#### France

- **Eric Abadie** | Director General | Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)
- **Emmanuel Caquot\*** | Former Head of Service for Manufacturing Industries & Postal Activities | Ministry of Economy, Finance & Industry
- **Pierre-Jean Lancry\*** | Former Director | Caisse Centrale Mutualité Sociale Agricole
- **Noël Renaudin\*** | Former President | Economic Committee for Health Products (CEPS)

#### Germany

- **Rainer Hess** | Impartial Chairman | Federal Joint Committee
- **Wolfgang Schmeinck\*** | Beauftragter des Vorstandes | National Federation of Company Health Insurance Funds

#### Italy

- **Ignazio Marino\*** | Senator & Chair of the Investigative Committee on the National Healthcare System (XVI Legislature) | Senate of the Republic of Italy

#### The Netherlands

- **Bert Boer** | Executive Member of the Board | College voor zorgverzekeringen (CVZ)
- **Mike Leers\*** | Former Chairman and CEO | CZ Healthcare Insurance Group
- **Diana Monissen\*** | Former Director-General, Ministry of Health | Welfare and Sport

#### Spain

- **María Luisa Poncela\*** | Former Deputy Director-General of Regional Incentives | Ministry of Economy and Finance

#### Sweden

- **Sören Olofsson** | Chief Executive Officer | Region Skåne
- **Ann-Christin Tauberman\*** | Former Director-General | Pharmaceutical Benefits Board

#### United Kingdom

- **Mike Farrar CBE** | Chief Executive | National Health Service Confederation
- **Sir Michael Rawlins** | Chairman | National Institute for Health and Clinical Excellence (NICE)
- **Professor Sir Mike Richards CBE** | National Clinical Director for Cancer & End of Life Care | National Cancer Action Team

\* denotes Network Alumnus

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## Network Members and Alumni continued

### Pharmaceutical Innovators

- **Bruno Angelici\*** | Former Executive Vice President, Europe, Japan, Asia-Pacific, Latin America | AstraZeneca
- **Ron Cooper** | President Europe | Bristol Myers Squibb
- **Eddie Gray** | President – Pharmaceuticals Europe | GlaxoSmithKline
- **Jane Griffiths** | Company Group Chairman – Janssen Pharmaceutical Companies | Johnson & Johnson
- **David Norton\*** | Former Company Group Chairman, Worldwide Commercial & Operations | Johnson & Johnson
- **Ulf Sæther** | Regional Vice President – Europe | AstraZeneca
- **Andrew Witty\*** | Former President, Pharmaceuticals Europe | GlaxoSmithKline

### Other Key Constituents

- **David Byrne** | Former EU Commissioner, Health and Consumer Protection
- **Sir David Cooksey\*** | Founder | Advent Venture Partners
- **Thomas Lönngren\*** | Former Executive Director | European Medicines Agency
- **Anders Olason** | President | European Patients' Forum
- **Sophia Tickell** | Director | Meteos Limited

\* denotes Network Alumnus

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## Breast Cancer Working Group

### Medical subject matter experts

- **Jonas Bergh**, Karolinska Institute, Sweden
- **PierFranco Conte**, Universitaria di Modena, Italy
- **Jindřich Fínek**, University Hospital Plzen, Czech Republic
- **Luca Gianni**, University of Milan, Italy
- **Anthony Howell**, The Christie NHS Foundation Trust, UK
- **Christian Jackisch**, Klinikum Offenbach GmbH, Germany
- **David Khayat**, Pitié-Salpêtrière Hospital, France
- **Jan Lubiński**, Pomeranian Medical University, Poland
- **Larry Norton**, Memorial Sloan-Kettering Cancer Center, USA
- **John Robertson**, University of Nottingham, UK
- **Karol Sikora**, CancerPartners UK, UK
- **Michael Untch**, HELIOS Klinikum, Germany

### Payers, regulators, health economists, and advisors

- **Johannes Bruns**, Deutsche Krebsgesellschaft, Germany
- **Karl Claxton**, University of York, UK
- **Pierre Démolis**, Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)
- **Harald Enzmann**, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Germany
- **Pavel Hroboň**, formerly Ministry of Health, Czech Republic
- **Bengt Jönsson**, Stockholm School of Economics, Sweden
- **Bertil Jonsson**, Medical Products Agency, Sweden
- **Sören Olofsson**, Region Skåne, Sweden

### Patient representatives

- **Els Borst-Eilers**, Dutch Federation of Cancer Patients, The Netherlands
- **Susan Knox**, EUROPA DONNA, European Breast Cancer Coalition (*OBSERVER*)

### Industry representatives

- **Jim Baker**, Johnson & Johnson
- **Alan Barge**, AstraZeneca
- **Paolo Paoletti**, GlaxoSmithKline

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## Diabetes Working Group

### Medical subject matter experts

- **Amanda Adler**, Institute of Metabolic Science, Cambridge, UK
- **Jean-François Bergmann**, Hôpital Lariboisière Paris, France
- **Christian Berne**, Uppsala University, Sweden
- **Bernard Charbonnel**, University of Nantes, France
- **Ele Ferrannini**, University of Pisa School of Medicine, Italy
- **Vivian Fonseca**, Tulane University Medical Center, USA
- **Philip Home**, Newcastle University, UK
- **Harald Klein**, Ruhr-Universität Bochum, Germany
- **Mohan Kumar**, NHS North Western Deanery, UK
- **Andrew Morris**, University of Dundee, UK
- **Eberhard Standl**, Munich Diabetes Research Institute, Germany

### Payers, regulators, health economists and advisors

- **Andrew Briggs**, University of Glasgow, UK
- **Hans-Georg Eichler**, European Medicines Agency (EMA)
- **Peter Kolominsky-Rabas**, University of Erlangen-Nuremberg, Germany
- **Félix Lobo-Aleu**, Universidad Carlos III, Spain
- **Noël Renaudin**, Economic Committee for Health Products (CEPS), France
- **Michael Schlander**, Institute for Innovation and Valuation in Health Care, Germany
- **Sjaak Verduijn**, CZ Insurance, The Netherlands

### Patient representatives

- **Maarten Ploeg**, Dutch Diabetes Association, The Netherlands

### Industry representatives

- **Martin Fitchet**, Johnson & Johnson
- **Gunnar Olsson**, AstraZeneca
- **Carlo Russo**, GlaxoSmithKline

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## Pilot participants

### Institutions by member state

#### France

- French Health Products Safety Agency (AFSSAPS)
- Economic Committee on Healthcare Products (CEPS)
- French National Authority for Health (HAS)
- Transparency Commission

#### Germany

- Federal Institute for Drugs and Medical Devices (BfArM)
- Federal Joint Committee (G-BA)
- German Centre for Health Technology Assessment and Public Health, U. of Erlangen-Nurnberg
- Paul Ehrlich Institute (PEI)

#### Italy

- Italian Medicines Agency (AIFA)

#### The Netherlands

- Healthcare Insurance Board (CVZ)
- Dutch Diabetes Association
- Netherlands Breast Cancer Association (BVN)
- Dutch insurers: Menzis

#### Spain

- Department of Pharmacy and Health Products, Valencia
- Federal Ministry of Health
- Ministry of Health, Basque Country

#### Sweden

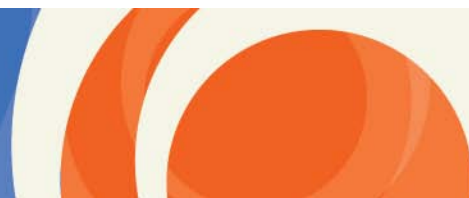
- Swedish Medical Products Agency (MPA)
- SKL Landsting County Councils
- Swedish Breast Cancer Association (BRO)
- Dental and Pharmaceutical Benefits Agency (TLV)

#### United Kingdom

- Genetic Alliance UK
- Medicines and Healthcare products Regulatory Agency (MHRA)
- National Institute for Clinical Health and Excellence (NICE)
- National Health Service Primary Care Trusts (Derbyshire, Redcar & Cleveland, Stockton on Tees)

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## Pilot participants continued

### Other constituencies

#### Pan-European

- DG SANCO Research
- European Medicines Agency (EMA)
- EUnetHTA (*Observer*)
- EUROPA DONNA (*Observer*)
- INFSO
- MEDEV

#### United States

- The Food and Drug Administration (*Liaison*)

#### Industry

- AstraZeneca
- Bristol-Myers Squibb
- GlaxoSmithKline
- Johnson & Johnson