

## Stewardship of health systems under pressure

### Executive summary

At the ninth meeting of the European Healthcare Innovation Leadership Network (“the Network”), participants considered the impact of the sovereign debt crisis on healthcare systems and the potential for transformative impact on the constitution and delivery of European healthcare. [Please see Appendix A for a list of meeting attendees.](#) Meeting participants also discussed the progress of pilots of multi-stakeholder consultations in drug development, focusing special attention on an early-stage therapeutic candidate for Alzheimer’s disease. Participants reflected on how the pilots have evolved over time and called for a rapid path towards the development of a sustainable platform for multi-stakeholder consultation.

The following is a summary of themes from the meeting:

- **The crisis threatens to have a long-term impact on health outcomes (page 2).** Participants acknowledged that the impact of Europe’s sovereign debt crisis on healthcare systems and patient health outcomes has been unevenly distributed across Member States and patient populations to date. Although some believe the effect of the crisis on health outcomes has not yet been extensive, many expect the impact to increase over the next several years. Participants identified a tension between short-term cost control measures and long-term health benefits. However, they acknowledged that the fiscal climate provided a timely opportunity to reconsider the delivery of healthcare fundamentally.
- **An effective response to the sovereign debt crisis may require a shift in stakeholder roles and relationships (page 5).** Participants agreed that the current environment calls for increased collaboration among stakeholders and suggested a number of ways to align priorities and integrate input from all constituencies, including patients. They discussed the importance of increasing predictability and insight into the scope of health interventions for which Member States were able to pay. Participants noted that greater transparency regarding Member States’ health priorities would enhance their ability as healthcare leaders to address unmet needs, improve the quality of patient health outcomes and maximise the efficient use of available resources. Participants believe the crisis renewed opportunities for stakeholders to identify and support value-based decision-making in healthcare.
- **There is significant momentum to develop a sustainable platform for multi-stakeholder consultations (page 11).** Participants discussed the evolution of the pilots of multi-stakeholder consultations in drug development through the lens of an early-stage Alzheimer’s disease medicine. The discussion highlighted the potentially devastating financial impact of Alzheimer’s disease on society in addition to its profound toll on patients and their caregivers. Participants also explored the future of multi-stakeholder consultations and the development of a sustainable platform to continue this work: *“We are at a crossroads, and there is a lot of work to be done to consolidate the pilot process.”* Many noted the growing

momentum to develop a more permanent process to conduct multi-stakeholder consultations.

### The crisis threatens to have a long-term impact on health outcomes

Long-term apprehension over unsustainable public debt levels among Member States has led to calls for greater collective oversight of budgetary discipline throughout Europe.<sup>1</sup> The unstable fiscal environment has increased the level of concern among patients, healthcare leaders, payers, health technology assessors (HTAs), regulators and industry representatives as they strive to improve patient health outcomes during a time of austerity. Given the severity of the crisis, participants suggested the Network devote a portion of the meeting to discussing the current economic climate, its impact on national budgets and the provision of healthcare and the effect that cost control measures are having on patient health outcomes.

Stewart Fleming, an associate fellow in the International Economics Programme at the Royal Institute of International Affairs, joined participants to provide a perspective over dinner regarding the economy and governance of the Euro area, the rapidly evolving debt crisis and the potential implications for European fiscal integration. Participants agreed that European leaders must *“do what is needed even when decisions made are unpopular.”* However some worried about the rise of technocratic governments to manage the crisis and ability of *“technocrats ... to maintain Europe’s hard-won social compact”* while making difficult resource prioritisation decisions. One budget holder expressed confidence in technocrats’ ability to navigate the current economic climate, noting: *“We would welcome a technocratic government.”* A civil society leader disagreed: *“Such support for technocratic leadership represents a fearsome erosion of democracy. [Technocrats] are not the ones who should make the decisions about the social compact in European countries.”*

The conversation continued the following day with an in-depth discussion of the effects of the economic crisis on health systems across Europe. Participants recognised that as a *“coalition of willing healthcare leaders,”* they have an opportunity to make choices that may mitigate the impact of the debt crisis on future health outcomes and may redefine how stakeholders work together to improve healthcare in Europe. One healthcare leader noted: *“In my country, industry and the health administration are not talking to each other because we do not have the right organisational arrangement on the ground. Still, in many countries where there is a divergence between the different stakeholders that have to identify how to move forward, there is a trend of people looking for a new organisational arrangement.”* To set the stage for tackling current and future economic turbulence, the Network focused on the following issues:

- The impact of the crisis on patient health outcomes
- The potential conflict between short-term cost control measures and long-term health benefits
- The opportunity for a more fundamental reconsideration of healthcare delivery

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<sup>1</sup> Daniel McDowell, [“The Financial Crisis of 2011: Why This Time is Different.”](#) *World Politics Review*, 14 September 2011.

### **The impact of the crisis on patient health outcomes**

Over the last four years, many Member States have been affected by the ongoing financial crisis. The impact varies across Europe. As one government official noted: *“There is a wide discrepancy across Europe. I am sure some countries will describe the impact as significant and others will not, depending on the strength of their healthcare systems before recent events.”* Greece offers one stark example of where the impact has been strongly felt. Fifteen years of consecutive growth in the Greek economy have been reversed, with observed reductions in access to healthcare due in part to 40% cuts in hospital budgets. There have been several health system breakdowns, including understaffing of healthcare facilities, shortages of medical supplies and bribes given to medical staff to jump queues in overstretched hospitals.<sup>2</sup> Between 2007 and 2009, the number of people able to obtain sickness benefits declined by approximately 40%, in part due to budget cuts.<sup>3</sup> According to findings published in *The Lancet*, “Overall, the picture of health in Greece is concerning. It reminds us that, in an effort to finance debts, ordinary people are paying the ultimate price: losing access to care and preventive services, facing higher risks of HIV and sexually transmitted diseases, and in the worst cases losing their lives.”<sup>4</sup>

One budget holder was concerned about the situation in his country: *“For the first time in [my country], there are thoughts of delisting medicines and medical technologies due to fiscal constraints.”* Another participant remarked, *“I am very aware of patients that are not getting the care they need as a result of the crisis.”*

For others, the crisis has not yet had much effect on healthcare decisions. One government official remarked, *“[The debt crisis] is just not getting taken seriously yet. We’re playing around the edge of rationing.”* Another added, *“Until now the effect of the crisis on my country has not been that significant.”* One healthcare official noted that *“the economic climate has resulted in lower uptake of new pharma products, but there remains significant growth in the uptake of medical devices and other tools.”*

Although participants’ perceptions of the impact of the crisis varied, most acknowledged that cuts in public healthcare budgets will become more significant in the future. One payer said, *“The impact [of the crisis] on patients is not significant now, but the way we apportion resources today may have a greater impact on health outcomes in two to three years.”*

### **The potential conflict between short-term cost control measures and long-term health benefits**

Participants observed that decision-makers labour under the burden of needing to implement short-term cost control measures while still protecting long-term health gains. One budget holder described a *“precautionary principle”* under which many decision-makers are operating: *“If you hold the budget and you are facing an investment cost up front, the rational response is to avoid risky purchases that are costly in the near term [and] have [only] an uncertain possibility*

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<sup>2</sup> Medical Xpress, [“Health Effects of Financial Crisis: Omens of a Greek Tragedy.”](#) 9 October 2011.

<sup>3</sup> *Ibid.*

<sup>4</sup> *Ibid.*

*of accruing benefits over the long term. As a public decider, you are going to consider withholding approval until you can resolve some of that uncertainty.”*

Others pointed out that local decision-makers face greater constraints when it comes to dealing with short-term economic pressures. A payer noted: *“Local prescribers are given annual budgets for which they are not allowed to run a deficit. I do not think they are going to be worried about what is going to happen in ten years’ time; they are going to be worried about meeting their budget constraints right now and keeping their jobs.”* Participants agreed that even while addressing short-term pressures, decision-makers should still maintain a longer-term perspective: *“You need to have the long-term agenda running even as you tackle the short-term crisis.”*

Another participant offered a long-term HTA perspective: *“Some [HTAs] will take a lifetime model and say this is a really good investment for the future. You may make initial losses from buying a particular product, but those initial losses are compensated for much later when you get gains in the form of health outcomes and resource savings in the future.”*

Although healthcare expenditures represent a long-term investment in the health of a population, in an era of severe fiscal constraint, some may be tempted to classify those expenditures solely as a cost. One health system leader noted: *“If you ask finance ministers, they see healthcare expenditures as a cost that uses a third of the budget. From my [healthcare] perspective, you always need 1% or 2% budgetary increase in health because of demographic reasons and healthcare demand on the system. However [finance ministers] will still see this just as another cost.”*

One HTA leader said: *“It seems to me that any expenditure on healthcare, if it is effective, is both an investment and a cost. It is a cost because it is an opportunity cost. You are taking it away from somewhere else, and there is something else you could have done with the money. It is an investment because it will produce a stream of benefits through time.”* He also suggested that arguing over whether an expenditure was an investment or a cost diverted attention away from more fruitful activities: *“[It] is an unhelpful distinction to make. We should concentrate on trying to see what we deliver for the money we invest and what we lose elsewhere. Focusing on these important questions will help us achieve the best health outcomes.”*

### **The opportunity for a more fundamental reconsideration of healthcare delivery**

Several participants were struck by the sense of urgency permeating European healthcare systems as a result of the debt crisis: *“There is an awful lot of talking and an awful lot of panic.”* One participant’s constituencies are *“very fearful about what is going to happen to [healthcare] systems that they feel are structured around certain basic shared principles. The fear is that you are going to lose that sense of shared societal outcomes.”*

A number of participants had a more hopeful outlook. One healthcare leader commented that *“the fiscal climate has created a sense of urgency but has also inspired a sense of opportunity.”* A government official recognised a shift among stakeholders’ perceptions about the prospects for change in healthcare: *“We could be on the cusp of breaking down some cultural and international taboos, things we never thought would change. Today, [the Network] discussed*

*the prophecy for fiscal integration or even the possibility of the United Kingdom joining the Euro. That we are having these discussions indicates a shift in what we now think is possible.”* Another participant asked: *“If [our] structural norms are shifting, what are the opportunities for regulatory integration [in healthcare], movement across international boundaries and increased patient involvement in decision making?”*

One industry leader believes that a new model will be necessary if healthcare systems are to continue to innovate amidst economic austerity:

*Financing the healthcare system to support innovation when there are insufficient government resources available is a substantial issue no matter how the debt crisis is handled. The question is whether a new model will emerge that will allow more innovation to come to market. If we are to provide 300–500 million citizens with quality healthcare, we need to rethink the model.*

An HTA leader agreed, adding: *“Many factors in the delivery of care are much more important to outcomes than new medicines. So if the squeeze is sufficient, we’ll get a radical rethinking of how medicines are used and how to define and achieve value for money in medicines and healthcare more generally across Europe.”* Overall, many agreed the time was right to shift stakeholder roles and explore new treatment and care delivery models: *“Never let a serious crisis go to waste ... Everyone is aware that now is the time for action [on reforming healthcare delivery].”*

### **An effective response to the sovereign debt crisis may require a shift in roles and relationships**

Although many participants agreed that healthcare reforms will naturally and necessarily emerge from the embers of the debt crisis, several questioned whether their current roles in the healthcare system need to shift: *“Would it be helpful for our roles to change and evolve? We have an opportunity to address these questions as we focus on responding to the current climate.”* Participants agreed on the need to increase collaboration. As one industry representative noted: *“We need to emerge from our individual bunkers and work together.”* During the discussion, participants suggested several ways to align and integrate efforts:

- Increase transparency and predictability regarding health priorities
- Renew decision-maker focus on understanding and supporting sources of value in healthcare expenditures
- Better integrate the voice of the patient into priority setting, value assessment and care management
- Consider new ways to organise healthcare delivery

### **Increase transparency and predictability regarding health priorities**

Participants identified the pilots of multi-stakeholder consultations as an important vehicle to clarify the value of a single medicine. However, they acknowledged that the consultations were not designed to address the collective unmet needs or overall therapeutic priorities of a national health system. Several participants urged more clarity on the package of health interventions that Member States prioritise and are likely to fund, with one industry representative stating: *“If there are unmet needs, we can address them. But someone in the healthcare system needs to first decide what’s in and what’s out [of publicly funded health systems].”* A payer agreed: *“Unless there is some sort of prioritisation on resource utilisation, there might be a reduction in the quality of outcomes or more likely a lack of progress in achieving outcomes.”*

However, prioritising health interventions to optimise health outcomes is a challenging issue with expansive potential scope. As one industry representative pointed out: *“‘Outcomes’ is a broad term. We should think about which geographies we are focusing on and what time frame is attached to any measurement.”* A budget holder agreed and stressed the need for specific metrics to determine the impact of a health intervention on health outcomes: *“The only thing we can conclude is that when you take a short-term view, the impact [of an intervention] on health outcomes may seem minimal. As more time passes, however, those impacts will increase. Until you have specific metrics it becomes difficult to conclude much more than that.”*

One HTA participant suggested that efforts to improve health outcomes by modifying healthcare services should focus on *“a small subset of outcomes that are amenable to how we deliver care.”* Regarding these outcomes, he asked: *“Can we actively maintain funding in areas where we can make a difference?”* A payer stressed the importance of effective use of available resources: *“All depends on how effectively you use the resources you have available.”*

Some expressed frustration at the *“tap dancing”* required to appropriately link new therapies to unmet medical needs. They lamented the resources and time spent trying to understand health system priorities and the cost of developing medicines that fail to meet them. Others highlighted the opportunity cost, in the current economic climate, of undesired products. One participant said: *“A failed drug is a complete waste of time and resources for all stakeholders in the health system.”* Another added: *“We could have used those invested resources to do something else, whether in healthcare or other productive uses. The more predictable [the system], the better for all of us.”*

Another challenge to priority setting is what one payer referred to as the *“growing gap between HTAs and payers. There is a danger that relationships that were actually improving within countries and across Europe will fragment, particularly in terms of standardising measurements of value for money.”* An HTA participant outlined the consequences of this rift: *“If the connection between HTAs and payers is broken, HTA bodies could engage in work and issue guidance that is essentially forcing cost-ineffective technologies down the throats of local healthcare providers, which displaces more health than is gained.”* To avoid such outcomes, participants called for enhancing stakeholder relationships to support increased predictability of a

future assessment process, reducing wasteful spending and allowing companies to innovate in ways that are responsive to society's needs.

Participants acknowledged the need for multi-stakeholder priority setting: *“Joint priority setting for the future is important so that those responsible for deciding what is valued and those responsible for creating the future seeds of value have a mutual understanding ... Companies that develop and commercialise products should understand [what research] activities [society values most highly].”* An industry participant concurred: *“The question is, ‘Do we have a contribution to make to a significant amount of unmet medical needs?’ I can bet our company has a contribution to make.”*

### **Renew decision-maker focus on understanding and supporting sources of value in healthcare expenditures**

The meeting uncovered a heightened and urgent need for greater clarity and alignment on “value for money,” due in large part to the effects of the European debt crisis: *“The current climate is accelerating the need to understand value. The increasing scarcity of resources forces you to think more about which valuable medical interventions are in development, which medical interventions are no longer offering value to patients and society and how we can ensure that resources are allocated to the former and not the latter.”*

The focus on defining value for money has accelerated the adoption of a number of pricing and market access approaches across Europe, including value-based pricing (VBP). While value-based approaches to rewarding innovation have been in place in a number of countries including Sweden, Germany, France and others, the United Kingdom's current focus on a VBP scheme is focusing renewed attention on value-based approaches within the UK and beyond. VBP seeks to understand and reward a new medical technology based on its value in a specific health context. [Please see Appendix B for a more detailed discussion of value-based pricing.](#) Karl Claxton, professor at the University of York's Centre for Health Economics, spoke with participants about the principles of VBP and its implications for value determination and price setting across Europe. Participants acknowledged the benefits a value-based approach to pricing but also noted that increasing reliance on VBP could lead to *“social inequality and reduced availability of certain drugs within value-based pricing countries.”*

#### **The social value component of value-based pricing in the United Kingdom illustrates the complexity of the approach**

The United Kingdom's approach to VBP is based on setting a maximum affordable cost per quality-adjusted life year (QALY) generated by the use of new medicines. Meeting participants raised several issues with this approach. Several noted the difficulty in accounting for the societal value of health in a VBP model: *“I do not know anybody who would claim that quality-adjusted life years as currently constructed could possibly capture all socially valuable aspects of health and healthcare.”*

*continued overleaf*

### The social value component of value-based pricing in the United Kingdom illustrates the complexity of the approach *continued*

One participant suggested a potential method for capturing social value: *“We ought to reflect [social] values by weighting the health that might be gained in particular areas, so [QALYs gained in] areas of high burden or severity should receive a higher weight than those QALYs gained in [areas of] lower burden or severity. Where there is a large therapeutic improvement, it ought to get proportionately more weight when calculating value based prices.”*

Some participants, however, did not feel that it was particularly important to include social value in a VBP model: *“Nobody believes that QALYs represent all aspects of social value. Trying to capture all aspects of social value will not overcome the problem of difficult allocation decisions, and more importantly, when it comes to value-based pricing, it will not change access to care. All it is going to do is change marginal prices a little up, a little bit down.”*

Participants discussed whether increased alignment on how best to determine value would aid an effective response to the sovereign crisis. They noted that the economic climate has incited many to consider once more how best to capture value in a time of diminishing resources. Given the growing impact of the crisis, participants raised two critical questions to understand further how best to capture and reward value across Member States:

- What is the opportunity cost of continuing with disparate pricing models for assessing value for money across national boundaries?
- How should value be rewarded over the lifetime of a medicine?

### Participants question the opportunity cost of continuing with disparate pricing models for assessing value for money in Europe

Although participants were interested in the United Kingdom’s efforts to align value with price over the long term, they questioned where VBP fit within a European pricing framework that already includes a number of other pricing models, including reference-based pricing. An industry representative noted: *“Part of the challenge here is that many European countries do not have the resources or capability to implement value-based pricing with any reasonable degree of accuracy. Several countries are referencing now because they do not have the wherewithal to take another approach.”* Others wondered whether VBP and reference pricing could complement one another: *“Reference-based pricing exists; it is utilised and is not likely to disappear with VBP. How well can the two co-exist?”*

Some participants acknowledged that pricing strategy will continue to differ among Member States. One participant noted: *“what you end up with is the big five [largest pharmaceutical markets in Europe], which have the capability for value-based pricing. Above those, what countries do in terms of reimbursement strategy is actually a political call.”* Others suggested that

countries lacking the ability to implement VBP could benefit from the value determinations of those that do: *“The practical application of all of this might be some definition of value from those who can do [VBP], with a kind of tiered referencing.”* Another participant challenged the group to consider a different model: *“Could we just end up with a system where the larger countries incorporate VBP and smaller countries with limited capacity to conduct these assessments can piggyback and reference the value-based price? This would create an opportunity for [reference-based and value-based pricing] to co-exist.”*

Some government officials expressed concern about the implications of having smaller countries rely upon the value choices of their larger neighbours. Participants recognised the importance of balancing consistency in valuation methodology with the need to incorporate individual country values. One long-term solution could be *“standardised health technology assessment early in the development process across all products and across all countries. Each country could choose its threshold level for adoption that would be reflecting what it values and what it can afford.”*

#### Stakeholders have an opportunity to identify and reward value better over a medicine’s lifetime

As health systems place greater emphasis on demonstrable value, the ability to develop evidence and assess that value in clinical settings grows in importance. As one participant noted in discussions leading up to the meeting: *“Only 30% of medicines demonstrate added value at the time of launch due to many factors – a lack of data being one. You frequently can’t understand the value at the time of launch.”* An industry representative added: *“That tension between demonstrating short- and long-term value is exacerbated, from a manufacturer perspective, by our [in]ability to get data. Some of it takes time. With these [multi-stakeholder] consultations, we are doing a better job of coming to the table with better data, but some of the outcomes just take time and an enormous amount of money.”*

Several participants emphasised post-launch evidence as an increasingly important means of demonstrating value: *“Showing real benefit in a clinical setting is even more important in this [economic] climate ... Post-launch value assessment will be more and more of a focus in Europe.”*

Participants agreed that post-authorisation value assessment will shift the roles of HTAs, payers, regulators and patients. Several commented on a lack of willingness on the part of some stakeholders to shift roles or invest human capital in such assessments. One regulator noted: *“The tools for post-launch assessment are already available in some areas. However, those with access to the data have not prioritised distributing it further. Perhaps the latest pharmacovigilance legislation will change that.”<sup>5</sup>*

Additionally, participants noted the need for richer engagement among stakeholders for HTAs to support a broad post-launch assessment model: *“HTAs should be incorporated into the post-authorisation management plans. However they do not have the systems, capacity or processes*

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<sup>5</sup> On 31 December 2010, the European Commission published new pharmacovigilance legislation. The legislation creates a Pharmacovigilance Risk Assessment Advisory Committee that makes post-authorisation efficacy studies mandatory where concerns relating to aspects of the efficacy of a medicinal product have been identified.

to do this.” This participant added, *“Ideally, regulators and HTAs would work together to understand post-launch benefits.”* Participants acknowledge the need to align the methods of rewarding value better across European Member States.

### **Better integrate the voice of the patient into priority setting, value assessment and care management**

Participants noted that the patient perspective is an indispensable stimulus for changing and improving health outcomes: *“Patients must be part of the [priority setting and value assessment] conversation if it is to go anywhere.”* Some criticised the status quo: *“The healthcare system doesn’t deliver. It doesn’t listen to us as patients.”* The question is how to incorporate the patient perspective: *“How can patients become more effectively engaged in value-based decisions? How do you include patients in regulatory discussions?”*

Participants identified an opportunity to increase efforts to elicit patient input into healthcare prioritisation decisions, particularly in a climate in which, as one payer noted: *“broadband cuts are made rather than a more nuanced prioritisation of resource utilisation.”* Several believed it was a topic that warranted further discussion, given the potential impact on cost control measures. One civil society leader noted: *“An empowered, health-literate patient is the cheapest citizen you can find.”* A patient advocate agreed, pointing out that patient groups are eager to *“muscle up ... and figure out what activity they can do in order to take charge of this.”*

### **Consider new ways to organise healthcare delivery**

As health systems respond to this turbulent economic climate, one HTA leader noted a new source of potential value: *“There is a whole mass of things in delivery of care that are much more important to outcomes than new medicines. So if the squeeze is sufficient we’ll get a radical rethinking of how medicines are used.”* Some participants challenged the group to shift their thinking on the structure of healthcare delivery. One healthcare leader stated: *“Healthcare is wrongly organised ... We currently have a health system that treats organs, not people.”* Not only would some participants like to see a more holistic approach to treating individuals, they also favour extending that holistic attitude to society at large. A health system leader noted: *“We have an opportunity within the industry to think about medicines in the context of whether they are helping to achieve the outcomes we want in the population as a whole.”*

### **The pharmaceutical industry could champion innovation in healthcare delivery**

Participants discussed whether the pharmaceutical industry should play a different role in the delivery of care and services. Industry representatives and senior public health officials asked: *“How can industry play a broader role than just the provision of medicine [and] really look at outcomes?”* One healthcare leader highlighted the pharmaceutical industry as the *“only major industry that has not transitioned from offering products to offering solutions amidst the current crisis.”* This leader called upon the industry to think proactively: *“Industry must decide how to get involved in health service innovation. You can stick to managing prices or even infuse more rational thinking in the determination of prices, but this does not transform healthcare delivery.”*

*Integrated care and population management transform healthcare delivery, and we have the tools to do this.” This leader noted: “There is a clear trend of health systems innovating on drugs, on clinical management, on the acute side of things, but very weakly on organisation of healthcare, so there is dyssynchrony in terms of innovation.”*

Another healthcare leader noted that actions taken to survive the current crisis are not sufficient to transform healthcare: *“My sense is that it is really important to manage efficiencies in the present crisis, but working on pricing, changing wages and tightening arrangements with providers does not transform healthcare. You need to create an organisation that transforms delivery around chronic patients, around patient engagement and integrated care.”*

#### **New organisational arrangements have the potential to improve healthcare delivery**

Participants agreed the structure of healthcare delivery could be modified to achieve greater impact at the population level. One healthcare leader mentioned an appetite in some regions to pilot a new organisational arrangement for disease management: *“There is interesting work around pathways from primary prevention to proactive management of pre-chronic conditions. There is a trend of piloting new partnerships, and some have taken this idea to the policy level.”*

A participant noted: *“Many industries are moving very strongly around how to manage chronic diseases, how to integrate care, how to bring things together basically in healthcare, but I do not see the pharma industry at all involved in that agenda.”* Some participants suggested the group consider appropriate business models for future partnerships: *“[This] question of a broader role of industry in the delivery of care is a theme. We have heard that again and again. I think it is an important opportunity to move ... from providing inputs to outcomes to impact.”* A health system leader expressed the need for collaboration: *“We should work with one another as individuals [HTAs, payers, public health officials and patients] who believe in the opportunity to change the structure and reconfigure the health system.”* Participants agreed to bring the resources of the Network to bear in order to make progress on these critical issues.

#### **There is significant momentum to develop a sustainable platform for multi-stakeholder consultations**

The meeting provided an opportunity for participants to discuss the evolution of the pilots of multi-stakeholder consultation through the lens of the Johnson & Johnson and Pfizer (“Alliance”) consultation on an early-stage Alzheimer’s disease medicine. Alzheimer’s disease and the associated issues of care for the ageing, and treatment of diseases of ageing more generally, are a looming crisis for healthcare. One participant said Alzheimer’s disease represented *“the perfect storm at the confluence of decreasing budgets and an ageing population.”* Alzheimer’s disease will be a tremendous challenge to healthcare systems, as it still remains *“100% incurable and 100% fatal.”* Its impact cannot be underestimated: *“Though we are all struggling with our healthcare budgets, if we do not solve this one problem, our healthcare budgets will be bankrupt.”*

The consultation on an early-stage Alzheimer’s disease medicine addressed major issues in drug development for this disease. Specifically, participants discussed issues around early, or

prodromal, disease and its implications for diagnosis, treatment, economic costs and accompanying health services: *“How could we intervene earlier in the disease? How could we have a better impact?”* Please see Appendix C for a more detailed perspective on the recent Alzheimer’s disease consultation.

The consultation revealed that *“the recent years have seen acceleration in both the science and the innovation of Alzheimer’s disease treatments.”* Clinical evidence presented at the consultation suggested that biomarkers available today, while still not perfect, *“have some reasonable utility in predicting who will progress to Alzheimer’s disease.”* Predicting this is critical, since intervening early with a disease-modifying therapy *“could result in a decrease in lifetime costs of therapy because it is clear the severity of [late-stage] Alzheimer’s disease drives the cost.”* However, participants in the consultation noted: *“Optimal outcomes in a complex disease are going to require more than just a pill or an infusion. We need wraparound services to improve outcomes by helping with cognitive remediation in the same way we provide physical rehab.”*

Participants in the consultation were impressed by the proceedings. One commented on the *“engaged participation of all the stakeholders. It was a new way of interacting.”* Another stated: *“I find the odd light bulb goes on inside my head when one of the clinicians says something, and I realise something I had not understood before. The consultation exemplifies the process through which particular learnings and understandings emerge.”*

Meeting participants reflected on the future role and direction of multi-stakeholder consultations. They agreed that with each consultation, *“there has been an evolution. There has been growth in mutual understanding over time.”* The discussions are *“better and more in-depth. The outcomes have become more useful for the companies.”* One participant said that the talks have been influencing policy, but suggested the initiative needs to do more: *“It is a clear priority for the [European] Commission and its Member States to have an early dialogue process to de-fragment the decision-making process for drug development. This is a key objective of EUnetHTA. They have learned much from the Tapestry initiative, but we need to make the process more systematic and to develop a methodology.”*

Others agreed and were eager to begin developing a methodology for an institutional platform (“sustainable platform”) to convene and administer future consultations: *“What else do we need to know before we begin to develop a methodology? Can we test the next set of pilot [consultations] against that draft-structured methodology?”* Another said: *“We can now create some joint methods with our HTA and [European Medicines Agency] colleagues.”* One suggestion was to *“organise one or two pilots under the auspices of DG SANCO [the Directorate General for Health & Consumers] or DG Enterprise”* to enable a greater breadth of HTAs and payers to join. Tapestry’s objective is to co-develop and pilot new ways of working for progress through sustainable, systemic change. Therefore, Tapestry will step away from the role of convener and secretariat for the consultations once a methodology for the institutional platform has been developed and applied in 2012.

Establishing a sustainable platform will not be easy. More than one participant raised the issue of representation and governance. *“There are some important HTA constituencies that have not been at the table, and we need to ensure that there is a full range going forward,”* remarked one. However, balancing representation with practical issues will be difficult. One participant asked: *“How do you create a governance process that works effectively with 27 Member States? We can’t have everybody around the table, so we will need some means to appoint rapporteurs. This raises a number of governance issues, and we do not yet have the answers.”*

Despite difficulties, the participants expressed a sense of urgency about creating the sustainable platform: *“We need to have a go as quickly as possible at a draft methodology.”* One participant suggested a practical approach: *“A draft methodology is like software. You start with a beta version and use pilot consultations to develop rapidly from version 1.0 to 2.0.”* Another brought the discussion back to the pilots: *“We have to go on with the pilots to focus not only on their content but also on the structure of consultations.”*

One participant offered this summary:

*This will be a progressive and iterative process that will require continuous learning and engagement. The pilots will need to continue providing advice on specific assets, but will also be necessary to help train and educate stakeholders across companies and agencies on a new means of engagement, a means of working across silos. The [sustainable] platform will allow stakeholders to focus on the question of value and the value proposition of new products. Ultimately, we expect that this will change the way stakeholders think and operate so that we have a more efficient means of bringing new and innovative products to market.*

Tapestry Networks is launching a Sustainable Platform Working Group comprising HTA, regulator, payer, patient and industry leaders in order to inform the development of a permanent platform for multi-stakeholder consultations. Participants agree a working group will provide an opportunity to address several design elements for the sustainable platform including appropriate resourcing, operational and governance models. The working group will provide periodic updates to the Network and will seek the Network’s support as needed for progress.

## Conclusion

The ninth meeting of the Network took place during a time of economic crisis, but participants believed the crisis could provide additional impetus for true systemic change: *“There are opportunities for true partnerships to develop how we can do things differently.”*

Participants were hopeful about opportunities *“to drive a higher level of innovation in healthcare,”* whether by augmenting the voice of the patient, increasing the predictability of health system needs, aligning on valuation systems in medicine or transforming the role of companies in healthcare delivery. All of these efforts will require *“a more fundamental look at how we deliver care”* and a commitment to *“new ways we can work together and think about value together.”* The multi-stakeholder consultations in drug development are examples of the value that can be realised through such collaboration. Participants expect that the pilots will lead

to a more systematic and sustainable approach to multi-stakeholder engagement in key medicine development issues.

Within the context of crisis, *“there is a sense of optimism. There are things to do.”* One participant stated: *“The Network could be an agent for change.”* Another concluded: *“The Network is a gathering of a group of individuals who have hope and who would like change to occur. I think that brings energy to me and gives me hope as well.”*

*The views expressed in this document represent those of the European Healthcare Innovation Leadership Network, a group of leading stakeholders from the public and private sectors committed to improving healthcare and economic wellbeing in the European Union and its Member States. This document is not intended to represent the particular policies or positions of the Network’s individual participants or their affiliated organisations. This material is prepared by and the copyright of Tapestry Networks. It may be reproduced and redistributed, but only in its entirety, including all copyright and trademark legends.*

## Appendix A: Attendees

The following members and guests attended the dinner before the meeting or the meeting itself:

- Ron Akehurst, Professor of Health Economics, University of Sheffield
- Rafael Bengoa, Regional Minister of Health & Consumer Affairs, Basque Government
- Jérôme Boehm, Policy Officer – Healthcare Systems, European Commission
- Sir Alasdair Breckenridge CBE, Chairman, Medicines & Healthcare products Regulatory Agency (MHRA)
- Karen Charman, Director – Business Development, NHS Confederation
- Professor Karl Claxton, Professor of Economics, Centre for Health Economics, University of York
- Ron Cooper, President – Europe, Bristol-Myers Squibb
- Bruno Flamion, Chair, Belgian Committee for Reimbursement of Medicines (CTG/CRM), FUNDP (Facultés Universitaires Notre-Dame de la Paix)
- Stewart Fleming, Associate Fellow, International Economics, Chatham House
- Eddie Gray, President – Pharmaceuticals Europe, GlaxoSmithKline
- Patrick Le Courtois, Head of Unit, Human Medicines Development & Evaluation, European Medicines Agency (EMA)
- Dr Hussein Manji, Global Therapeutic Area Head – Neuroscience, Johnson & Johnson
- François Meyer, Director, Health Technology Assessment Division, Haute Autorité de Santé (HAS)
- Anders Olauson, President, European Patients' Forum
- Sir Mike Richards CBE, National Clinical Director for Cancer & End of Life Care, National Cancer Action Team
- Ulf Säther, Regional Vice President – Europe, AstraZeneca
- Ad Schuurman, Head of the Business Contact Centre, College voor Zorgverzekeringen (CvZ)
- Paolo Siviero, Head - Strategy & Pharmaceutical Policy, Agenzia Italiana del Farmaco (AIFA)
- Sophia Tickell, Founder & Director, Meteos Limited
- Spiros Vamvakas, Head of Scientific Advice, EMA

## Appendix B: Understanding value-based and international reference pricing systems

In 2009, many Network members predicted that the economic crisis would lead Member States to emphasise value assessment when making reimbursement decisions. Others worried about the emergence of pricing models disconnected from broader considerations of value.

Today, multiple Member States are exploring or have introduced value-based pricing (VBP) and international reference pricing (IRP; also referred to as external reference pricing) as tools to assess medicine value and control healthcare expenditures. VBP is pricing of therapies such that the health benefits to patients, providers and society exceed the health outcomes displaced elsewhere due to the additional cost.<sup>6</sup> IRP systems are not explicitly equipped to value new treatments. Rather, Member States that use IRP use prices set by other countries to determine their own reimbursement price for a given pharmaceutical.

The following pages provide a discussion of each model and the implications for patients, budgets and support for value-added innovation.

### Value-based pricing

The VBP model requires a clear definition of value in order to progress to the price-setting stage. However, before value can be determined, a number of questions must be answered, including how to define value, when and how often to assess value, and the merits of flexible pricing and risk sharing.

#### Defining value in a value-based pricing system

Value-based pricing is designed to ensure “that the prices paid for medicines are based on an assessment of its value, looking at the benefits for the patient, unmet need, therapeutic innovation and benefit to society as a whole,” according to UK Health Secretary Andrew Lansley.<sup>7</sup> However, as one member observed, although price should be linked to value, “*different systems will see different value and set prices accordingly.*” Another member noted the importance of context within the healthcare system: “*Value-based pricing must not be considered in isolation of the total resources of a healthcare system. It must consider the resources available to spend on drugs, not just what the potential value might be.*”

Many applaud the effort to account for societal benefits that are not reflected in the current system – for example, the well-being of caretakers or impact on workforce participation. However, others point out that as the concept of value expands from therapeutic value to include economic and societal benefits, so does the complexity and uncertainty surrounding the

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<sup>6</sup> Ginette Camps-Walsh, Inge Aivas, and Helen Barratt, *Improving UK Patient Outcomes: How Can Value-based Pricing Improve Access and Adoption of New Treatments?* (London: 2020health, 2009), page 9.

<sup>7</sup> Department of Health (UK), “[Patients to Benefit from New Drug Pricing System.](#)” news release, 16 December 2010.

approach used to determine value. One member expressed it thus:

*What seemed to be a great metric, the assessment of value, has proven to be problematic. To what standard are we making the assessment? Is there more societal value in a medicine catered to men who earn more than women? If a treatment disproportionately benefits the unemployed, is it less valuable to society? I think these are questions that need to be addressed before moving to value-based pricing.*

Another member highlighted the importance of having multiple perspectives, including that of patients, on hand to address the difficult question of how best to allocate value: *“It is not enough for government to steer the discussion. Patients need to be stewards of not just their health, but of their health systems. They should contribute to this discussion [on value].”*

The UK Department of Health, which has adopted VBP, has outlined a “QALY-plus” approach to pricing based on setting a maximum affordable cost per quality-adjusted life year (QALY) generated by the use of new medicines. According to the health economist Adrian Towse, “The ‘plus’ aspect would take into account a drug’s ability to achieve one or more of the following: tackle a disease that entails a substantial ‘burden of illness’; constitute ‘greater therapeutic innovation’; and demonstrate ‘wider societal benefits.’”<sup>8</sup>

Members noted that currently, *“only The Netherlands, Scandinavia and the UK use a QALY-like measure. France and Germany have historically taken a very different approach.”* For a more comprehensive discussion of the complexity of value assessment, see the September 2008 ViewPoints: *“Aligning Perspectives on Value.”*<sup>9</sup>

### Assessing value pre-launch and post-launch

Once the boundaries of value have been defined, regulators and HTAs rely on evidence to inform their assessment. However, often there is insufficient evidence at launch for a meaningful assessment. One member noted that *“only 30% of medicines demonstrate added value at the time of launch due to many factors, a lack of data being one. You frequently can’t understand the value of a medicine at the time of launch.”* Several members emphasised post-launch evidence as an increasingly important means of demonstrating value: *“Showing real benefit in a clinical setting is even more important in this [economic] climate ... [The challenge is] “to maintain or optimise value in clinical reality. Post-launch value assessment will be more and more of a focus in Europe in part due to the development of new pharmacovigilance legislation.”*<sup>10</sup> One member suggested formally dividing assessment into pre- and post-launch components: *“Can we divide value assessment into two phases, what happens before approval and what happens post-approval? There will be mandatory post-launch efficacy studies in the future.”*

<sup>8</sup> Adrian Towse, *“Value-based Pricing in the UK.”* Office of Health Economics, 11 January 2011.

<sup>9</sup> European Healthcare Innovation Leadership Network. *“Aligning Perspectives on Value.”* ViewPoints, 16 September 2008.

<sup>10</sup> On 31 December 2010 the European Commission published new pharmacovigilance legislation. The legislation introduces a Pharmacovigilance Risk Assessment Advisory Committee which, amongst other changes, requires the mandatory conduction of post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of a medicinal product have been identified.

Members have questions, however, about how post-launch value assessment would be implemented. One member had questions about the role of HTAs: *“HTAs should be incorporated into the post-authorisation management plans. However, they do not have the systems, capacity or processes to do this.”* This member added, *“Ideally, regulators and HTAs would work together to understand post-launch benefit.”* Another member observed, *“There is no system for follow-up in the market, so how do we demonstrate value if there was uncertainty at the time of launch? So far, the pilots [of multi-stakeholder consultations] have tried to minimise this uncertainty by clarifying what data are needed to evaluate a medicine at the time of launch. But uncertainties will remain.”*

#### Enhancements for VBP: flexible pricing and risk sharing

Some argue that the price of a medicine should change in response to changing value assessments over time – effectively a flexible pricing model. Initial prices could, for example, increase in response to new evidence of efficacy during the patent life.<sup>11</sup> Conversely, prices could decrease in response to evidence of limited effectiveness. One healthcare leader noted the difficulty of raising the price of a medicine once in circulation: *“Some countries do not have a legal mandate that allows this type of price increase. Other countries just do not, in practice, increase prices regardless of circumstance.”*

In the case of medicines whose value assessment goes down, there is the additional problem that it can be difficult to remove a medicine once it is on the market unless there are safety concerns. One member observed, *“Ultimately, a value-based pricing assessment could [reveal that] a product is not delivering value.”* This member asked, *“Will a company raise objections or cause a media storm if we pull it from the market?”* Patients and clinicians may also fight the withdrawal of a medicine if there is any evidence or perception of benefit.

Members also noted a rise in risk sharing between payers and medicine developers. Risk sharing provides early access to therapies and partially insulates the payer from uncertain health outcomes and financial impact by encouraging the continued development of evidence: *“Risk-sharing is the new normal – more than 50% of recently launched medicines in my country have some sort of risk-sharing agreement, often limiting initial volume.”* Unlike simple price revisions, risk-sharing agreements diminish the impact on payers’ budgets until uncertain health outcomes are clarified: *“[There is] increasing reliance on risk shares in my country, as we want to be very careful about assuming any new costs before we truly understand the benefit of a new drug.”*

#### International reference pricing

Unlike VBP, IRP does not include value assessment as an explicit component. Instead, IRP provides institutional purchasers and price setters with a target, benchmark or reference price based on prices of similar medicines in other countries.<sup>12</sup> Rather than directly negotiating price

<sup>11</sup> David Taylor, *Implementing Value based Pricing for Medicines: An Introduction* (London: School of Pharmacy, University of London), page 7.

<sup>12</sup> See Jaime Espin, Joan Rovira and Antonio Olry de Labry, *WHO/HAI Project on Medicine Prices and Availability* (Geneva and Amsterdam: World Health Organization and Health Action International, 2011).

with a medicine developer, countries determine price based on a range of factors, including a mean of referenced countries, lowest price across countries and median price, among others. Within the EU, Germany, Sweden, and the UK are the only nations not using IRP.

The European Federation of Pharmaceutical Industries and Associations (EFPIA), in response to a report on pricing commissioned by the European Parliament's Committee for Environment, Public Health and Food Safety, affirmed use of IRP, saying, "It is rational for a Member State without the resources to assess the value [of a medicine] to refer to a similar country that does [have the resources to make a value assessment]."<sup>13</sup> Members agreed: "*Clearly there is a role for reference pricing, particularly between countries and markets that are similar.*" Another added, "*Reference pricing is an easy way to remove political pressures from price negotiations.*"

Several members questioned the appropriateness of high-income countries referencing countries with significantly lower purchasing power: "*Reference pricing is used by some systems that want to make sure they are getting the lowest possible price ... But it is not appropriate for Germany to reference Greece, for example.*" Others pointed out that IRP leads to price convergence: "*Prices are converging in Europe due to [IRP] practices. This convergence is a problem if it creates a race to the bottom after which no one is willing to pay for research.*"

#### Secondary impact of IRP

IRP may successfully reduce pharmaceutical expenditures, particularly for countries that use countries with lower purchasing power for their reference prices. However, the benefit accrued may be offset by other costs. Medicine developers may, for example, elect not to launch in a particular market if they believe that the price they receive from that market will have a disproportionately negative impact on their global pricing strategy. One member summarised the problem: "*When budgets are strapped, people look for short-term savings. The more strapped budgets become, the more countries will drive pharma companies down to the marginal cost of production, which may not be sustainable. There is a danger of referencing a very low-cost Member State and halting drug development.*" Another member gave an example: "*Some products were not launched recently in Germany because of concern over the reference price implications outside of Germany.*"<sup>14</sup>

#### The UK's role as a reference country

Although the UK uses VBP to determine pricing, it serves as a reference country for 25% of the global market. Subsequently, any definition of value in the UK is reflected in countries that reference the UK: "*If you are part of the large group that references the UK, you are watching closely to see how value-based pricing is implemented. Indirectly, this assessment of value becomes yours, regardless of how similar your countries are.*" In other words, VBP countries have significant influence in a region that relies heavily upon IRP.

<sup>13</sup> Generics and Biosimilars Initiative, "[Europe's Industry Concerned about Converging Prices and Patient Access.](#)" 20 May 2011.

<sup>14</sup> In 2011, Boehringer Ingelheim and Eli Lilly decided not to launch their new diabetes drug Trajenta in Germany due to Germany's new pricing controls. See Ed Schoonveld, "[Does a German Launch Make Sense?](#)"

Several members voiced concern over the difficulty of reconciling VBP and IRP in Europe. An industry representative asked, *“What do you do when some countries are genuinely interested in value and many others are in favour of international reference pricing?”* Another member asked, *“How do these two models sit together? Are they compatible? How does it work when some countries emphasise value and others reference the lowest-price countries in order to set their own low prices with little regard for value?”* One industry member asked whether *“developed markets accept that they need to pay a higher price for medicines than developing markets. The key question is who pays what share for new medicines?”* A healthcare leader asked if *“different countries in Europe should pay different amounts for the same medicine”* and said, *“That is a dangerous question, as it will unsettle the current system. I would prefer in the future if there were one European price.”*

## Appendix C: Unlocking value through multi-stakeholder consultations - the July Alzheimer's disease pilot

In an era of constrained resources, addressing the significant financial cost of Alzheimer's disease (AD) treatment and care is critical. In 2010, the global costs<sup>15</sup> of AD rose to €453.5 billion per year, consuming more than 1% of worldwide GDP.<sup>16</sup> Many experts have proposed early diagnosis and treatment of AD as an effective tool to mitigate the social and economic impact of the disease, with recent economic modelling suggesting that the benefits of early identification and intervention could exceed the related costs of early treatment.<sup>17</sup> In July, a multi-stakeholder pilot consultation focusing on a novel treatment programme targeting early-stage AD patients convened as part of the pilots of multi-country, multi-stakeholder consultations in drug development. This consultation built on previous Network discussions on the impact of AD and the related diagnostics. The following section contains a brief summary of the Network's recent engagement with AD and a more detailed description of the multi-stakeholder conversation on AD.

### A history of the Network's discussions of AD

Since its inception, the Network has addressed AD in its discussions of areas of high unmet need. In 2008, members considered AD for a Working Group candidate, with the goal of creating a "shared value framework" for AD similar to those developed for breast cancer and type 2 diabetes.<sup>18</sup> Ultimately, members concluded that scientific understanding of the disease was not sufficiently advanced for a thorough and concrete discussion on value. However, a recent set of scientific discoveries and emerging diagnostics has increased interest in early-stage AD. At the January 2011 meeting, members explored whether public healthcare systems should pay for a diagnostic that can accurately predict who will develop AD when no proven effective therapy yet exists. Members discussed reimbursement considerations in both clinical and research settings and agreed that further collaboration would be necessary in this area of critical unmet need, noting that *"diagnostics and their associated biomarkers are key to understanding disease progression and ultimately curing Alzheimer's disease."*

In January, the Network endorsed a proposal to reserve the second set of pilot consultations for those issues in drug development that had the highest impact on patients and society. Consistent with the spirit of this recommendation, participants gathered in London at the EMA on 1 July 2011 for a multi-stakeholder consultation on an AD treatment being developed by Janssen Alzheimer Immunotherapy and Pfizer ("the Alliance"). Participants discussed the clinical development programme and implications for market access and reimbursement for a treatment programme for patients with prodromal AD, an early stage of the disease.

<sup>15</sup> Costs were attributed to informal care (unpaid care provided by family and others), direct costs of social care (provided by community care professionals and in residential home settings) and the direct costs of medical care (the costs of treating dementia and other conditions in primary and secondary care).

<sup>16</sup> Martin Prince, Renata Bryce and Cleusa Ferri, *World Alzheimer Report 2011* (London: Alzheimer's Disease International 2011), page 4.

<sup>17</sup> *Ibid.*, page 5.

<sup>18</sup> European Healthcare Innovation Leadership Network, *"Aligning Perspectives on Value,"* pp 19–20.

### The July pilot

The July pilot consultation was the first multi-stakeholder consultation to consider issues related to the development of a treatment programme for patients with prodromal AD. Participants included regulatory representatives from the EMA, Agenzia Italiana del Farmaco (AIFA, Italy), Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM, Germany), Medical Products Agency (MPA, Sweden) and National Authority of Medicines and Health Products, IP (INFARMED, Portugal); HTA and payer representatives from AIFA, National Institute for Health and Clinical Excellence (NICE, UK), Menzis (the Netherlands) and the Dental and Pharmaceutical Benefits Agency (TLV, Sweden); subject matter experts and patient advocates from France and the UK; and representatives from the Alliance development team. The meeting was co-chaired by Professor Ron Akehurst (University of Sheffield) and Professor Bertil Jonsson (Uppsala University), representing HTA and regulatory perspectives, respectively. The core themes of the consultation were clinical characterisation and outcomes in prodromal AD, the need for long-term data in reimbursement assessments, and strategies for the management of AD patients.

After the consultation, participants noted the value the consultation provided as an open forum for learning. A representative from the Alliance stated, *“I find this process extremely valuable ... I think collaboration is going to be essential [in AD medicine development].”* A regulator remarked, *“What we achieved is fantastic,”* and an HTA representative commented that *“it has been interesting to see different stakeholders and their different perspectives.”* A clinical expert did note the challenge of *“coming to a consensus, so if this is an objective, it will require longer meetings or fewer questions.”* However, several participants emphasised the importance of holding open discussions and, as one person put it, *“really understanding different points of view.”*

A payer explained the value of a multi-stakeholder forum:

*[Such a forum is] almost mandatory for this particular type of disorder and therapy, and for the times we are in. There is no way we could address the level of complexity inherent in the biology of the central nervous system without putting together the resources that are here in this room and [communicating] private to public, public to public, and private to private ... I do not think the current model is working ... We [need to] change in a revolutionary way the way we are approaching this.*

### Looking ahead

Participants in the July consultation agreed that a multi-stakeholder approach would be optimal when addressing the challenges of effective AD diagnostics and treatment development. Several participants expressed interest in creating a multi-stakeholder Working Group to delve deeper into critical issues and to develop potential AD policy guidelines for screening, diagnostics and how to value treatments that take place at different points in disease progression. One pilot participant noted that the pilot would address *“a societal problem that we have to share and own ... We hope to come up with a partnership that allows us to understand what is the best path*

*forward ... There is an opportunity to make a real and meaningful difference.”* The Network is eager to embrace this challenge.