Forming Value-Based Agreements in the UK

Value-Based Agreements: The Future of Life Sciences Deals in the UK?

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Context

We are living through an era of astounding innovation and disruption in life sciences and health care. Perhaps inevitably, these trends present healthcare systems with unprecedented opportunity to improve clinical and health economic outcomes—and in some cases to transform how these outcomes are achieved. They also raise questions about value and risk posed by new healthcare technologies and entirely new technology categories. How, for instance, should healthcare systems think about pricing new gene therapies or immunotherapies which are potentially curative for previously difficult to treat chronic diseases—and which can do so with a single course of treatment? How to approach the risk associated with investing in fascinating, but still emerging, molecular diagnostic technologies capable of diagnosing serious disease years before current available technologies –and possibly years before relevant treatments are available?

As the development of diagnostics and therapeutics with significant promise and uncertainty continues, healthcare systems and life sciences companies need to move beyond traditional cost-per-unit and rebating models, in order to manage this uncertainty while ensuring rapid access. We have seen this happen most prominently through the development of more flexible and creative deals, or value-based agreements offering novel forms of risk-sharing between companies and health systems. These can take a range of forms—for instance contracts that are contingent upon the value or outcomes that the therapy delivers to patients and payors, and/or upon the continued generation of evidence around the efficacy of the therapy—or both. Such value-based agreements are becoming increasingly popular across the globe—including in the UK, where the NHS has recently struck a number of large-scale value-based deals and signalled an increased interest in similar, future agreements. This demand, by some of the life sciences industry's most important institutional customers, underscores a critical business priority to rapidly develop the capabilities for such agreements.

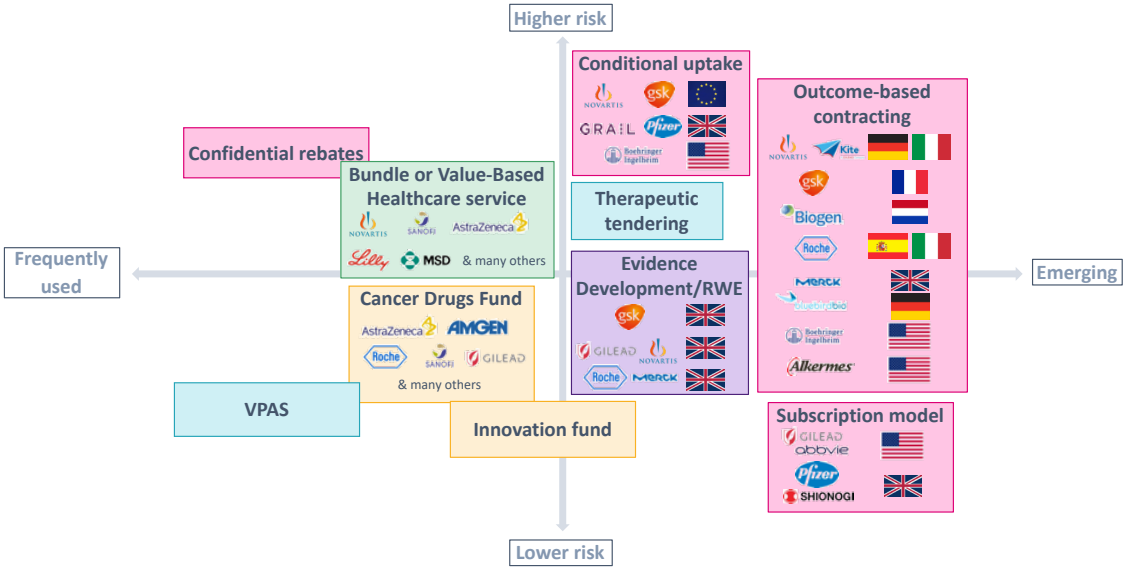
In this article, we explore the definition and types of value-based agreements in greater detail, the status of such deals in the UK, and important requirements for forming and implementing successful value-based agreements.

What are Value-Based Agreements?

Value-based agreements (VBAs) encompass a range of deals/circumstances between healthcare systems/payors (such as the NHS) and life science companies that incentivise the healthcare system by 1) managing key uncertainties around products or therapies and the risk attached to them, 2) addressing healthcare system priorities in specific therapeutic areas, 3) providing additional data for the evaluation of medicines/therapies, and/or 4) driving local priorities through improved outcomes.

Essentially, VBAs are innovative contractual arrangements—often framed and characterised as strategic partnerships between payors/providers and life science companies—which can be agreed in principle before or after regulatory approval and health technology assessment, and which are focused on delivering improved health economic value, transcending fixed-cost-per-unit and rebating practices. Many different types of VBAs exist, and they have been around in one form or another for decades. Their scope or focus may embrace a particular therapy or an entire disease or patient population, and they may be struck at a national level or a sub-national/local level.

Figure 1. Different archetypes of value-based agreements, with select local and international examples



Source: CF analysis

Why focus on VBAs now?

VBAs have been around for many years. During this time, however, the levels of interest of healthcare system and life sciences companies in forging such deals--and their ability to execute them--have been varied and to a certain degree cyclical. Since 2015 in particular, renewed interest in VBAs has emerged, resulting in an upward trend in forming and utilising VBAs. This renewed interest results from a number of factors, including;

- The remarkable scale of on-going innovation in life sciences, bringing significant new opportunities in biologics, gene and cell therapy, immunotherapy, genomics and other medical diagnostics, together with other technology categories. Significantly, important parts of this impressive innovation is accompanies by marked uncertainty around clinical and economic value
- The extraordinary financial pressure faced by payors/healthcare systems, including the NHS, especially in the wake of the COVID-19 pandemic. For public sector payors, this increases the normal imperative of managing public expenditures in prudent ways—including by exploring innovative contracting.
- In Europe, North America and Australasia, health technology assessment agencies are considering the merits of transitioning from one time technology appraisals to a "Health Technology Management" paradigm. This shift involves early consultation between health technology agencies and industries, mechanisms to support innovation and the development of methodologies that can adapt to new technologies, and collection and assessment of real world evidence (RWE). More guidance is issued with conditional recommendation pending further evidence generation.
- The challenges associated with demonstrating the clinical utility of emerging technologies (e.g., genomic molecular diagnostics, and a renewed focus on precision healthcare to better manage risk and improve outcomes in specific patient populations with important unmet needs, etc.
- The emergence of the era of Big Data, as well as increased intellectual and healthcare system sophistication in thinking about, assessing, and actually using RWE
- Increased healthcare system focus on and ability to deliver precision medicine, enabling the unmet needs of specific risk-stratified patient populations to be better addressed.
- A desire for the Life Sciences industry (at both a company-level and a sector-level), healthcare systems, regulators, and HTA agencies around the world to forge stronger partnerships to better address unmet patient needs and create more resilient healthcare systems

- The emergence and enhancement of evolving public and private sector policy and business models focused on developing new approaches to pricing and pricing-related partnerships. These range from government-based efforts and initiatives such as the AAC And VPAS in the UK and pending US pricing reform to price-focused life science companies such as EQRx and data health tech companies sharing profits with healthcare systems that make their datasets accessible.

Where does the UK stand on VBAs?

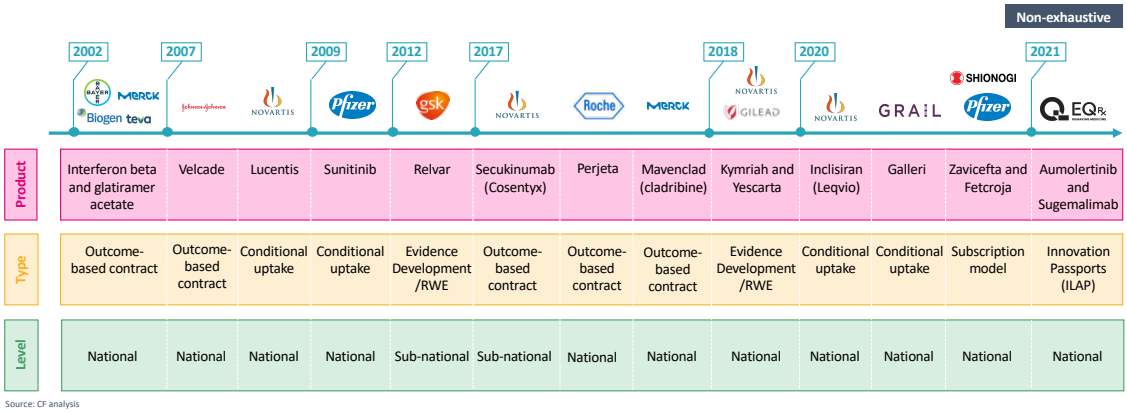
Internationally

Other countries have had significant and long-term experiences with national VBAs, most frequently in Oncology, Haematology, Cardiovascular diseases, Endo/Metabolics, and Rheumatology. Italy's AIFA, a VBA pioneer, has pursued or required outcomes-based contracting, the generation of real word evidence, or similar agreements for certain innovative medicines for 10 to 15 years. The country has entered into several dozen VBAs over an even longer timeframe and continues to innovate its VBA-oriented approaches and capabilities. Other European nations, such as Germany, France, Spain, Sweden, and Denmark, have made consistent, targeted use of VBAs for over a decade to improve access and support further evidence generation and have given VBAs renewed attention in recent years. In the US, Medicare and private insurers—some of which manage tens of millions of patient lives and frequently pilot agile new approaches to address financial and clinical uncertainty across technology categories – have engaged in more than 50 publicly-announced VBAs over the last two decades. Indeed, approximately 20 to 30 per cent of leading US payors have implemented or are implementing some kind of VBA. Many others are in discussions with life science companies about potentially doing so.

In the UK

The UK has had a similar scale of VBAs as some of its peer European nations, including a large number of local-level VBAs with individual Clinical Commissioning Groups/Integrated Care Systems—at times designed and delivered with relatively limited publicity. In contrast to this local-level success, UK national-level VBAs have received greater publicity but over time have also developed a mixed track record. In part, this arises owing to challenges in design and operational complexities in execution. These challenges—which many other private and national healthcare systems also face--have included difficulties in conceiving of or agreeing upon a proper focus for the deal (clinical endpoints, risk-sharing details), difficulties in implementation and operationalisation (data to be tracked, mechanisms for such data tracking, changes to care pathway, administrative burden on the NHS), and a lack of clear understanding between the NHS and LS companies about the motives and priorities behind the VBAs. And of course, the all-important issue of price.

Figure 2. Select examples of national and sub-national VBAs in the UK over time (non-exhaustive)



Source: CF analysis

A more favourable environment

Like other healthcare systems, the NHS is experiencing a range of changes making the country an increasingly favourable environment for value-based agreements. First, NHS and NICE senor leadership have adopted more innovative and agile approaches to supporting increased access—exemplified by

mechanisms for more rapid HTA review, contingent recommendation pending further evidence development, funding emerging health tech categories and therapies, and a series of high-profile, “smart" pricing deals. In addition, the NHS ecosystem is implementing leading-edge national data capabilities. These drastically improved during the pandemic, and continue to do so, with a marked shift to data-driven guidelines in partnership. The shift to Integrated Care Systems (ICSs) signals a willingness to improve the planning and delivery of health and care and opens up a new realm of possibilities, including new types of pricing innovation and collaboration. Beyond these developments, the successful partnerships that were forged between the LS industry and the NHS during the pandemic--and in other key areas such as genomics and long-term research--have laid a foundational for successful collaboration. Finally, the life sciences industry has renewed its focus on the UK as a critical global reference market.

These changes signal a strong willingness to shift the approach to making deals with LS companies in the UK, as well as the motivation to handle more complex deals that can drive better patient outcomes and deliver better value for money. Just as importantly, at an NHS ecosystem-wide level they signal significant emerging VBA agility and capability to deliver.

High-profile UK examples

Select recent examples of UK VBA activity, including the vision to pursue and development of the capabilities to support these partnerships, include the following:

***Mavenclad*, Merck**

In 2017, NHS England stuck a precedent setting outcome-based deal with Merck for its multiple sclerosis (MS) drug Mavenclad, making the UK the second fastest country in the world, after Germany, to make this drug available. The deal came after NICE’s final recommendation for this drug to treat people with rapidly evolving severe relapsing-remitting MS. Mavenclad’s list price was set at over £2000 per 100mg tablet--a price on which the NHS will have received a significant discount on through this deal. Though the commercial details of the agreement remained confidential, following through on it depended on outcomes data being generated by the NHS. Previously, the healthcare system had struggled with the development of such data, owing to the state of its IT infrastructure and data collection practices. As such, a crucial aspect of the successful execution of this deal was to create digital data hubs across the country to enable the NHS to generate the required evidence.

***Kymriah and Yescarta*, Novartis and Gilead Sciences**

In 2018, Novartis and Gilead were both looking to get their two CART-T therapies (Kymriah and Yescarta respectively) approved for patients with blood cancer. Though NICE approved Kymriah as the first CAR-T available in England to children and young adults with B-cell acute lymphoblastic leukaemia (ALL), it had first recommended against the use of both therapies in adults as they did not meet the UK’s cost-effectiveness standards. However, NICE later approved patient access to Yescarta in adults on the condition that the therapy be managed through NHS England’s Cancer Drug Fund (CDF) after confidential price discounting. This agreement made Yescarta the first CAR-T therapy available to adult blood cancer patients in England. With this deal, an estimated 200 adult patients per year with diffuse large B-cell lymphoma (DLBCL) and primary mediastinal B-cell lymphoma (PMBCL) who have failed at least two prior therapies will be eligible for the treatment. Though Yescarta’s list price was set at £300,000 per patient, Gilead will have made pricing concessions to obtain CDF support. Significantly, this VBA put the NHS at the forefront of providing one of the most promising new cancer therapies—and one that is individually tailored to each patient.

***Inclisiran*, Novartis**

In January 2020, the UK government announced a collaboration with Novartis to launch a clinical trial for Inclisiran, a first in class investigational treatment for hyperlipemia in adults that can decrease the risk of future cardiovascular events as a result of reduced LDL-C. The deal included an access agreement for high-risk patients, a large-scale trial carried out by NHS England, and the creation of a consortium with academic groups to try to improve manufacturing of drugs like Inclisiran in the UK. In September 2021, NICE approved the new cholesterol lowering therapy for a particular risk-stratified patient population—patients with primary hypercholesterolaemia or mixed dyslipidaemia who have had a previous cardiovascular event. As a result, the therapy will be made available to 300,000 NHS patients

over the next three years, subsequently rising to nearly half a million people. Analysts estimate that Inclisiran could prevent 55,000 heat attacks and strokes, saving 30,000 lives by 2030

***Galleri*, Grail**

In late 2020, Grail announced a partnership with the NHS to help transform cancer outcomes by making Galleri – a simple but technologically sophisticated blood test that can detect over 50 types of cancer, over 45 of which lack recommended screening today, with a low false positive rate – available to UK patients in 2021. This blood test has the potential to enable earlier treatment, which in turn is often a driver of improved oncology outcomes. The NHS-Galleri trial was launched to assess how well the new test works in the NHS. On one level, Galleri can be thought of as a large-scale commercial research pilot that is both (1) necessary to demonstrate proof of concept at a population level and within particular care pathways and (2) very difficult to perform without the partnership of a large healthcare system. The commercial partnership program aims to confirm the Grail test works as expected to detect cancer in patients without symptoms, as a precursor to its routine use by the NHS. It is one of the largest trials of its kind, with a target of 140,000 participants covering about half of the UK geographically. Significantly, a range of prominent stakeholders are involved, including:

- Grail itself (the main funder and organiser of the trial and developer of the Galleri test);
- NHS England who will provide follow-up and care related services to the trial as well as data through the National Disease Registration Service; and
- a team of cancer researchers from Cancer Research UK and from King's College London Cancer Prevention Trials Unit, who will coordinate the trial and analyse results.

As this suggests, Galleri is a striking NHS-life sciences company partnership and a precedent for the joint development—and risk sharing—for exciting new technology categories.

***Early subscription-based agreement to address AMR: Zavicefta and Fetcroja*, Pfizer and Shionogi**

In 2019, the NHS and NICE announced that they will launch a trial of the innovative 'subscription-type' payment model for Antimicrobial resistance (AMR). AMR refers to the process by which microorganisms develop defences against antimicrobial drugs, enabling these microorganisms to adapt and become resistant to treatment. Using this kind of "Netflix" payment approach will mean moving the NHS away from paying for individual packs of antimicrobials and, instead, making an annual payment based on the health benefits to patients and the value to the NHS. Proposing a subscription model served to incentivise companies to invest in this critical area, with the objective of securing a pipeline of future treatment options for NHS patients. As an early phase of pursuing this model, in 2020 the NHS and NICE selected two treatments, Cefiderocol (Fetcroja) manufactured by Shionogi, and ceftazidime with avibactam (Zavicefta) manufactured by Pfizer, to move to an innovative health technology evaluation process, followed by the design and rollout of a a subscription-based payment model. The details of this model are currently being finalised, but will likely ten-year contracts. According to these contracts, the NHS will pay a fixed annual fee of £10 million for access to the two medicines, regardless of how much is used to treat patients. This flat fee has been calculated based on the value that the therapies offer the health service.

Significantly, this VBA is one of the first of its kind globally—underscoring the UK's innovative and leadership in the area, and providing critical LS industry incentives to invest in AMR therapies.

Long-term partnership with EQRx

In October 2021, the NHS signed a Memorandum of Understanding with EQRx, a start-up life science company which has received significant global attention owing to its mission to "develop and deliver important new medicines to patients at radically lower prices" than are available today. The MOU included an expressed intention by both parties to enter into a long-term, strategic partnership to secure UK patient access to EQRx's pipeline of innovative and cost-effective cancer medicines. More pragmatically, it also granted EQRx's lead oncology pipeline assets--- aumolertinib (indicated for non-small cell lung cancer, gastric and oesophageal cancers, and natural killer T-cell lymphoma) and sugemalimab (an EGFR inhibitor for non-small cell lung cancer) —the first ever issued Innovation Passports providing access to the NHS's new Innovative Licensing and Access Pathway (ILAP). ILAP will provide EQRx and its two oncology assets with prioritised, on-going engagement with the key decision-making institutions in the UK regulatory and access ecosystem. It may also result in an accelerated

Marketing Authorization Application (MAA) assessment for aumolertinib and sugemalimab as well as rolling review and a continuous benefit-risk assessment. In other words, it provides the basis for the NHS and EQRx to strike some kind of VBA regarding each therapy.

Forming and implementing VBAs

UK perspective: why pursue a VBA for a new therapy?

As the above suggests, there are many reasons for healthcare systems and life sciences companies to consider pursuing a VBA. LS companies need to consider, anywhere between 6 and 24 months before submission to NICE and NHS England, which potential benefits pursuing a VBA route would reap for their technology. We list some of the most prominent benefits below:

- A new technology or entirely new technology category is under consideration—which has strong NHS interest but is also associated with some significant uncertainties in its clinical and economic case for adoption.
- Taking a population or risk-stratified sub-population view improves the clinical or health economic case
- The value for money case may improve with further future evidence, including RWE
- The price may be considered cost effective by NICE and the NHS, but the healthcare system itself is concerned about budget impact
- Adoption of the therapy within the NHS implies significant future change to the relevant care pathway
- There is an opportunity to partner at the local-level to address key unmet population needs—e.g., through increased diagnosis, treatment, etc within the care pathway
- There is potential to further improve the overall case (clinical, health economic, operational, pathway) locally, beyond NICE standards
- The price per patient is deemed appropriate, but the NHS is concerned about budget impact

UK barriers and challenges

While the UK is becoming a more favourable environment for forming innovative VBAs, some barriers and challenges, which have impeded the successful development execution of VBAs in the past remain.

First, while in the UK, the NHS and the industry share an ambition to improve access and outcomes, the methods and processes for achieving full alignment are not yet fully agreed. This is a common challenge across countries, though the UK, at least, is actively addressing the challenge.

Second, VBAs are operationally complex to implement, largely owing to the data requirements to assess impact and provide a basis for risk-sharing payments, and the understandable need to minimise disruption to NHS care pathways. They can also be expensive, time-consuming and complex to design, and it can be difficult to understand the details of the proposed scheme.

Third, life sciences companies often do not consider VBAs early enough in the therapy development and commercialisation process, which is related in part to a failure to seek early NICE advice and to challenges in navigating NHS guidance and the innovation support ecosystem (including institutions such as the Accelerated Access Collaborative, Office for Market Access). Related to this, life science companies internally often lack standing capabilities and processes for planning, designing, and implementing Value-Based Agreements. To a certain degree, this is an issue of incentives for VBAs, as well as understanding of the customer's (i.e., the NHS) interest in them.

Finally, the recent NHS focus on high profile, strategic smart deals (large population or high-profile diseases, new technology categories such as gene therapy) while important, may also mean missing a whole category of mid-sized deals when national-level agreements are difficult to strike. Currently, these mid-sized deals take the form of sub-national VBAs at the CCG/ICS level).

Criteria for successful VBAs in the UK

Though it is difficult to guarantee the success of a VBA, recent and past experience as well as the direction and priorities of the health system in the UK point to several conditions which, if fulfilled, would improve the likelihood of aligning various stakeholder ambitions and successfully agreeing on a deal.

1. **Meets company's strategic objectives for the technology:**
   - Establishing a VBA would address key strategic and competitive imperatives and (global, national, and local) uncertainties, including the seven priority mission areas identified in the new UK Life Science vision (Cancer, Cardiovascular, Mental Health, Dementia, Respiratory, Vaccines, and ageing)
   - The timeframe for positive VBA financial impact is acceptable for the company itself and the NHS
2. **Consistent with NHS Innovation and Strategic Priorities for the disease area**
   - There is considerable financial, clinical, and health economic value at stake
   - The proposed deal reflects and aligns with NHS therapeutic area (e.g., unmet need in cardiovascular diseases, cancer, obesity, CV/T2D) and focus priorities (e.g., genomics, health inequalities, innovative evidence generation/RWE). For instance, such deals could be a driver to motivate action against health inequalities, reducing variability in access pathways across geographies, ethnicities and deprivation quintiles.
   - Precedent setting projects that will raise the UK's profile and innovation for NHS England and the UK healthcare ecosystem as a whole
3. **Addresses potential challenges in demonstrating clinical and or cost effectiveness**
   - Therapy currently does not meet NICE's health economic threshold for recommendation, or there is substantial uncertainty about its ability to do so
   - Therapy access for critical patient population/unmet need (including health inequities) is not addressed or is insufficiently addressed by existing mechanisms)
4. **The provisions likely to be incorporated into the agreement can be implemented in the NHS**
   - Simple in details with low administrative and operational burden, and a care pathway that lends itself to the right data collection and results verification, based on existing or emerging technology and RWE (i.e. clear/acceptable endpoints, data easy to obtain, limited and acceptable change to existing care pathways and procedures)
   - Necessary clinical/health economic outcomes can be demonstrated in an acceptable timeframe
5. **Interest of relevant patient communities:** Relevant patient communities will support the agreement
6. **Basis for alignment**
   - Positive relationship/dialogue between key NHS and NICE stakeholders for disease and LS company
   - Basis for NHS and LS company agreement on how to share outcome and financial risk, desired clinical/health economic outcomes, which outcomes to pay for, etc.
7. **Stakeholder engagement:** Engaging with the right stakeholders at different levels is necessary to bring such arrangements to fruition
   - National stakeholders (from NICE, NHS England, relevant national initiatives and clinical thought leaders, etc): To discuss proof of concept and scale-up, new and complex treatment, high uncertainty and potential
   - Existing organisations/entities: Work out potential mechanism, or incremental use of existing mechanism, such as:
     - The Accelerated Access Collaborative (AAC): a unique partnership between patient groups, government bodies, industry and NHS bodies, working together to streamline the adoption of

new innovations in healthcare, which serves to get more proven innovations into the hands of clinicians and patients, faster, and make the NHS a great place to innovate to accelerate the development of valuable innovations for citizens

- Innovative Licensing and Access Pathway: a new pathway which aims to accelerate the time to market for leading-edge new therapies through sustained, on-going engagement between innovator life science companies, the MHRA, and other key NHS/DoH ecosystem institutions (e.g., NICE, the SMC, NHS England and NHS Improvement, Health Research Authority, the National Institute for Health Research etc.
- Cancer Drugs Fund (CDF): a source of funding for cancer drugs in England that provides access to promising new treatments, via managed access arrangement, while further evidence is collected to address clinical uncertainty, and Interim funding for all newly recommended cancer drugs, giving patients access to these treatments many months earlier than before
- Innovative Medicines Fund: will be expanding the CDF to other therapeutic areas, allow patients to have early access to the most clinically promising treatments without the need for lengthy assessments

– Integrated Care systems: Work out what can be done/co-design approach and on the ground, operational details

– Leading key option leaders: Work out what can be done/co-design approach

What needs to be in place to develop a VBA in the UK?

Once a LS company decides to pursue a VBA, its leadership team should address several practical issues. These include developing and crystallising the proposition and focus of the VBA, determining the stakeholders that will need to be engaged and mobilised, and identifying the data requirements for the success of the deal. Additional, more specific questions to consider include the following:

Proposition and Incentives

- What aspects of the current situation incentivise the health care service to go beyond just agreeing a discount? Why should it seek a VBA?
  - Is there significant uncertainty around the value of the technology?
  - Is the healthcare system currently paying a lot for medicines?
  - Are the right patients not getting access to the technology?
  - Is the healthcare system not using its data collection capability to validate health economic impact of the technology?
  - Does some other obstacle or some form of inertia in the current care pathway or HCP/ICS preference exist?
- Does the proposed arrangement improve the lives of patients? Does it support physicians and nurses in providing better care and enabling better clinical outcomes? Does it meet critical strategic priorities of the healthcare system?
- What specifically s being proposed specifically in the care pathway/therapeutic area by the VBA? What specific risks and uncertainties are addressed? What value is created (e.g., unmet need, precision health stratification, preventative potential, improvements in clinical/HE outcomes, releasing NHS resources, clinical utility, etc)? What incremental benefit results to the healthcare system and the life science company?
- What specific improvements in clinical/HE outcomes will be the focus of this agreement and in what timeframe? Are these meaningful/relevant for pathway and readily measurable?
- What are the proposed commercial arrangements? How will the value and risk be shared between the parties—and during what timeframe?
- How can uniform uptake be ensured? Is there an opportunity to co-develop the product with the NHS? To partner after marketing authorisation and NICE assessment to enable appropriate HCP adoption?

- What will the NHS need to do to ensure that the agreement delivers on its potential? What will the LS company need to do?

Stakeholders, Governance, and Execution Capabilities

- Who needs to be involved to deliver the agreement? Have all necessary stakeholders from each side (NHS and company) agreed to its design and details? What is the view of patients and patient organisations regarding these?
- What roles will each key stakeholder have in on-going governance, operations, and performance monitoring? What mechanisms exist for these?
- Is each side (NHS and company) satisfied that the other has the necessary capabilities to execute and fulfil its role in this partnership?

Data

- What data needs to be collected and how?
- How will data be used to assess program impact and inform required financial payments?
- Under what conditions will each party have access to the program data? Will they seek a joint publication approach?
- How are the capabilities required accessed?

Conclusion

The currently emerging value-based agreements are innovative contracts – and partnerships – that allow for increased flexibility in managing risk around the evaluation, initial adoption and life cycle management of new technologies. Significantly, many of the key UK VBA principles and questions described in the sections above can also be adapted to other national healthcare systems. Despite the complexity of forming, agreeing and implementing such deals, VBAs are becoming an increasingly important means of enabling access to new technologies. Practically, this means that life sciences companies will need to invest in the capabilities to enter into such deals. Having more VBAs will mean getting the right medicines and technologies to the right people, and therefore driving better patient outcomes.

About the authors

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