
RWE in Europe Paper II:

The use of Real World Evidence in the disease context

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Abstract

Real World Evidence (RWE), the use of data not collected via traditional randomised controlled trials (RCT) for decision-making, is becoming more interesting to market-access and reimbursement decision-makers, despite potential methodological issues around its use. This paper, the second in a series looking at the use of Real World Evidence (RWE) in Europe, analyses the opinions of a number of key experts in pricing and reimbursement from a selection of countries across Europe. Discussion centred on the use of RWE in licensing, commissioning, clinical decision-making and patient and outcome related decision-making in the context of three different treatment areas – chronic disease, oncology and rare diseases. Results of discussion sessions with ‘RWE experts’ indicated that the associated benefits of RWE are becoming more relevant but there is a need for a well-organised, high quality system for data generation, interpretation and use. It is likely that different treatment areas will have differing RWE requirements and differing levels of utility. In the rare disease arena, RWE may have a role in licensing based decisions, but this is unlikely for chronic disease or oncology. In order to enhance the role of RWE, and to ensure it meets its full potential in all treatment areas, a multi-stakeholder approach at the EU level is required, with collaboration between national and supranational organisations and all stakeholders including patient organisations, manufacturers and reimbursement agencies.

Contents

Abstract	1
Contents	2
Introduction	3
Method	4
Results	4
Session 1: Licensing	5
Chronic diseases.....	5
Rare diseases.....	6
Oncology.....	6
Session 2: Commissioning	7
Chronic diseases.....	7
Rare diseases.....	8
Oncology.....	9
Session 3: Clinical decision-making and guidelines	9
Session 4: Patients and outcomes	11
The role of industry.....	12
Leadership through action.....	12
Developing credible data.....	13
Growing the community.....	13
Concluding remarks	14
References	14
Acknowledgements	15
Author affiliations	15

Introduction

Real world evidence (RWE) – traditionally defined as “data used for decision-making that are not collected in conventional RCTs” ISPOR/(Garrison *et al.* 2007)¹ – is increasingly recognised as a valuable source of evidence for both market access and reimbursement decisions, despite the presence of methodological difficulties such as a lack of randomisation, bias, inflation of treatment effects and issues around data quality (Pietri & Masoura 2014). Randomised clinical trials (RCT) – generally seen as the preferred data generation tool – have restrictive enrolment criteria, limited generalisability, increasing complexity and overly controlled study environments. Their use is a particular issue in orphan conditions with small populations and chronic diseases with long-term data outcome requirements.

Following on from a “*Payer RWE voice of the customer project*”, which gained insight into RWE needs and priorities across ten European markets, six contributors with significant experience in specialist disease areas and commissioning of care, as well as prior experience in the field of RWE, participated in a discussion group, held in London in June 2016, to garner opinion on the use of RWE in Europe. During the day-long meeting, the group discussed the following four topics: (a) Regulatory implications and the role of RWE; (b) RWE processes and implementation in decision making; (c) Meaningful outcomes from RWE; and (d) Priorities for focus and opportunities for industry cooperation and partnership.

Discussion at the June 2016 meeting highlighted that RWE was used to some extent in all European countries represented, generally in the areas of accelerated access and re-review. It was not seen as a clear substitute for RCT data but the advent of increased chronic conditions – such as cancer – has the potential to alter the paradigm somewhat. With the time taken to gather evidence on outcomes (i.e. overall survival), lengthening as a result of life extension, and the accelerated development of drugs for orphan conditions, with small patient groups delaying recruitment to traditional RCT, RWE may begin to play a stronger role (Gill *et al.* 2016).

Whilst the initial meeting, in what will likely become a series of RWE-related focus sessions, answered certain questions around the use of RWE in Europe in both commissioning and licensing decisions, it also highlighted some additional gaps that need further attention. For example, how do we address the gap between licensing and commissioning? How can RWE address these two different questions? How do we incorporate patient data in the most effective way? How can data be used to improve the value of medicines? How does RWE translate to improved outcomes and value for patients? How well is RWE accepted in specific scenarios as complementary or in support of RCTs? The current study aims to address some of these gaps and gain additional insight around therapy-specific RWE use. This additional insight required the participation of patient groups, decision makers, proxy payers and policy makers with the aim of understanding how commissioning decisions are driven and how they are influenced by national policy.

¹ RWE can also incorporate diagnostic, prognostication, and causality related data.

Method

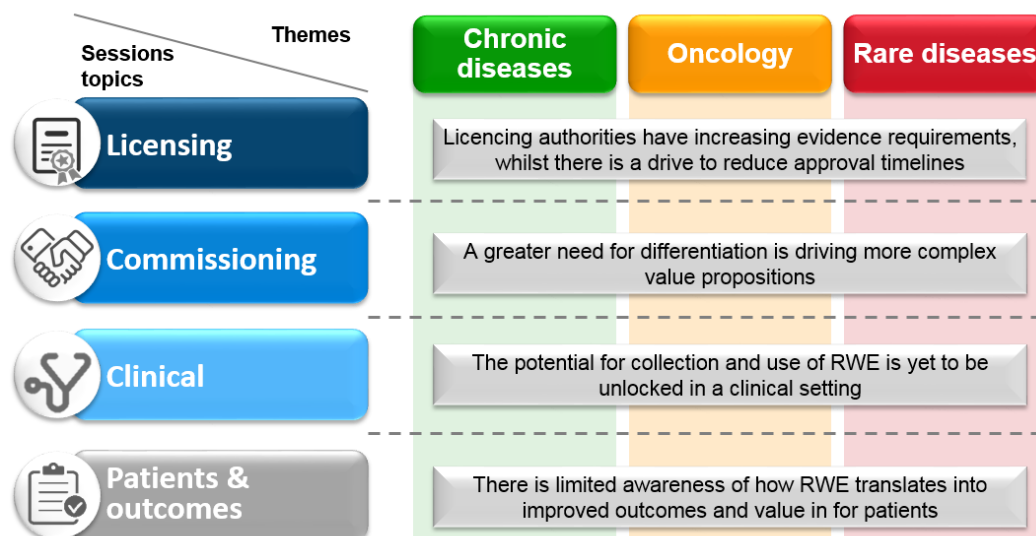
A selection of contributors with significant experience in specialist disease areas and commissioning of care, as well as prior experience in the field of RWE, were invited to participate in a discussion group to garner additional opinion on the use of RWE in Europe within the context of three specific condition-related themes. Via a day-long focus-group discussion in London in December 2016, 12 participants, from ten European countries, addressed a number of specific topics across four sessions. Attendees included those from Austria, the Czech Republic, Germany, Hungary, Italy, Poland, Portugal, Spain, Sweden and the United Kingdom with representation from academia, health services, government bodies, patient organisations (PO) and payers. As described this meeting followed on from a similar insight-building meeting held in London in June 2016. Six of the attendees at the meeting described here contributed to the June 2016 meeting and were therefore invited back to gain further understanding of their experience with RWE.

An hypothesis driven approach was used to explore the role of RWE in three treatment areas (chronic disease, oncology and rare diseases) across the product lifecycle. Topics covered included: (a) Licensing; (b) Commissioning; (c) Clinical; and (d) Patients and Outcomes. Each of these sessions consisted of a topic introduction presentation by one of the delegates followed by a combination of group breakout sessions, with set questions to be addressed, and opportunity for plenary feedback.

Results

Figure 1 highlights the structure and focus of each meeting topic across the three condition areas, chosen to highlight the different data requirements for licensing and commissioning for different therapy areas.

Figure 1: Meeting session structure



Within each of the four sessions, which mirrored the stages of the drug approval pathway, there were a set of questions used to guide the discussion process with the expert contributors. Results from each of these sessions will now be discussed in turn.

Session 1: Licensing

The specific focus in this session was the use of RWE in licensing decisions. The acceleration of approval processes and the need to reduce complexity may produce new opportunities for RWE. However, whilst increasing attention is being paid to non-RCT data in terms of licensing decisions the use of RWE varies between countries and trade-offs are required – generally due to the lack of randomisation that is a characteristic of RWE. It may be possible to compensate for this lack of randomisation but these possibilities can be reduced in licensing-based decisions due to the length of time required and the small populations in use. Selection bias is also an issue, with limited effective and reliable methods for correction.

Three questions guided discussion in this session: (1) *How can RWE contribute to licensing medicines within the treatment area of interest?*; (2) *How can RWE improve access and reduce timelines and/or complexity?*; and (3) *What will increase the legitimacy of RWE in licensing?* These were discussed in three breakout groups based on the three therapy settings.

Chronic diseases

Chronic disease patient cohorts tend to be large and, as a result, there is the potential for greater levels of RWE-based data, which could provide robust evidence for any licensing decisions. However, in licensing terms patient benefit and drug safety are the key concerns, and the fact that larger patient cohorts are available means that RWE tends to be used secondarily to the more traditional RCT data. Furthermore, by nature chronic diseases have longer-term outcomes meaning that the use of RWE in a pre-licensing situation may be limited, although there may be a place for it to model data outcomes, rather than as a complete replacement of RCT.

It is more likely that in the context of chronic disease RWE will be used as a conditional requirement in licensing to support reimbursement. Decision makers could focus more on using RWE for modelling purposes, rather than for pure-efficacy related purposes, or for validation purposes. For example, for extrapolation of safety data in cases where molecules are very similar and safety data already exists, such as biosimilars.

To increase the legitimacy of RWE in terms of chronic disease there needs to be a rationale in place. Improving the consistency of data gathering, data quality and data utilisation, through experience, ensuring transparency and defining minimum collection parameters and standards for valid data sets, which may

differ by disease or treatment area, may all increase RWE legitimacy for licensing. Furthermore, including the patient voice, in the form of PO, in data collection for licensing to add to the robustness and ‘authority’ of the evidence and developing cross health sector ‘guidelines’ for RWE standards could also be beneficial. Expert contributors concluded that RWE comes second to clinical trials but that it may become a conditional requirement, adding to the information gathered via RCT, rather than acting as a replacement, as long as the minimum data set standards are defined and that there is sufficient transparency.

Rare diseases

Between the three treatment areas of focus, RWE was thought to have the most potential in the rare disease arena in terms of licensing as there are certain situations where RCTs are not feasible. The consensus amongst the expert contributors was that the rare disease licensing system is not strictly ready for the contribution of RWE. Essentially, there is no agreement on who is responsible for funding and organising data collection and as a result there is limited data collection due to lack of incentive. RWE could be used in a conditional licensing arena, useful in rare diseases, which generally have limited time to play with in terms of data generation, as it can generate higher levels of data in a shorter period when compared to RCT.

To increase RWE legitimacy there needs to be an increase in the available data. If registries were enhanced, and included information on diagnosed patients and resulting treatments, not just the drug in question, then data quantity would increase. Incentivising registry completion could enhance data availability. Experts suggested that paying physicians for entering patient diagnosis/treatment information or giving health systems a share of pharmaceutical company revenue if they assist with data collection might incentivise the completion of registries. Similarly, collaboration across countries between experts in rare diseases may enhance data collection possibilities. There is also a need to help patients understand RWE better as the majority of data will be coming from them. The patient community has started to talk about RWE but they are not yet fully informed.

Finally, there may be opportunities to involve RWE in certain conditional-access style schemes whereby, following Phase II trials, experts who agree to collect additional data on the specific treatment are allowed to prescribe novel agents, in advance of country wide prescriptions being made available in order to prevent RWE data from being ‘lost’.

Oncology

As with discussion around rare diseases, oncology specialists stated that a key challenge with licensing and RWE is the need to improve registry data as it is difficult to translate Phase II results into clinical practice. The consensus was that

RWE use could become very important but that decision-making was sluggish with licensing authorities having room to produce more directional guidance on the contribution RWE could make. Some experts suggested a supra-national regulator, which could provide novel directional guidance.

There are also clinical challenges around the use of RWE for licensing. There is a certain level of scepticism amongst clinicians around the use of RWE and they have difficulty investing time measuring and recording data that may not be meaningful if continued. Ensuring patients understand what RWE can do for them, and identifying how they can contribute, may increase its perceived legitimacy.

Session 2: Commissioning

This session concentrated on the use of RWE in commissioning decisions, where a greater need for differentiation is driving more complex value propositions. Commissioning in this context relates to the process of financial decision-making (rather than the reimbursement decisions that determine costs when the drug is used in the real world). In certain situations, specific commissioning bodies are limiting the use of RWE. For example, in England political pressure is forcing the health technology assessment (HTA) body the National Institute for Health and Care Excellence (NICE) to perform HTAs before a drug is licensed, meaning there is no RWE available for incorporation in any form of decision-making.

RWE could be used to enhance and validate finance-based decisions in a form of trial extension. For example, patient follow-up on those who had taken part in randomised trials. Experts all agreed that there was a requirement for different approaches to medicine funding and that there was an overall need for patient, clinical and economic evidence. Having an understanding of these gaps may enable the collection of relevant RWE to contribute to commissioning decisions.

To further guide discussions in this session, three questions were addressed: (1) *How can we use commissioning to support reimbursement?*; (2) *How can industry support the optimisation of registries to enable commissioning?*; and (3) *What is required from RWE to support HTA decisions?* Again, these were discussed in the context of the three treatment areas.

Chronic diseases

The consensus amongst experts during the discussion was that the challenge with chronic conditions when it comes to RCT for drugs that treat these types of conditions is that patients are living longer, although not always consistently within countries, and often have multiple confounding conditions. As a result, a paradigm shift in the way that commissioning works for chronic conditions is required. New commercial propositions, such as pay for performance may be required.

As things stand, despite being important, patient data tends not to be universally considered in HTA decisions, and there is limited evidence of drug price increases as a result of RWE. RWE may have a role in supporting patient experience endpoints, particularly where other differentiating factors such as efficacy are equitable, articulating social benefit, controlling the use of a drug or monitoring guideline implementation.

One issue with the use of RWE in commissioning is the fact that registries are generally set up for clinical, rather than commissioning, purposes. As mentioned previously registry quality can vary significantly. To improve this situation data collection or supply could be incentivised, or lack of collection could be disincentivised, whereby reimbursement will be reduced for healthcare practitioners that do not collect suitable data. In chronic disease registries, used for commissioning purposes, the focus should be on the data required, the size and proportion of a population represented and the eventual value and purpose of the data to ensure that the correct data is collected. Peer supported data collection may also reinforce compliance with data collection.

However it is collected, it is important that any RWE is non-biased, robust and consistent and must include relevant endpoints, agreed on by multiple stakeholders including payers, patients, industry and clinicians. There is the possibility of using cross-border data sets, but these may require the collection of too many data points. It may be more suitable to use RWE that is country, or region specific. Finally, experts determined that RWE collection should be a requirement of conditional reimbursement, which could result in faster decision-making.

Rare diseases

Discussion around rare disease centred on the involvement of patients in HTA decisions to ensure the 'patient' voice is heard. Within this context there may be a significant role for PO, although their contributions vary across countries due to both ability and resource of the different patient groups. For example, in the UK patient preferences play more of a role in decision-making than they do in Germany, where the HTA body does not accept RWE. Patient groups tend to be used for quality of life sampling, rather than clinicians, as the ethical approval required to use NHS data makes it easier to go directly to the patient. However, it is vital that any patient group involvement goes above a purely emotion based input and that they contribute to data collection.

Industry should work towards integrating RWE into the HTA process, alongside RCT data, from the start, in the form of the value dossier. Data collection could be made mandatory by law, which would increase the volume available. Similarly, industry, alongside insurance companies, could support the financing of registries, although there may well be some conflict of interest issues if the company that is submitting the dossier of evidence is also sponsoring the collection of registry data.

Oncology

Discussions around RWE use in commissioning of oncology pharmaceuticals confirmed some of the issues highlighted during discussion of RWE in both rare disease and chronic illness therapy commissioning. For example, quality and availability of registries is key for the enhanced incorporation of RWE into HTA-type decisions. Data or registry ownership is not clear-cut, which needs to be addressed. There also needs to be a methodology in place for registry building, with unambiguous responsibilities in terms of ownership and clear guidance on how data needs to be used. Facilitating cross-national discussion around best practices in terms of data collection may be useful, as will showcasing best practice and developing methods of homogeneous cross-country registration, which may provide wider support for RWE use.

There was tacit agreement that RWE could aid in positioning and reimbursement-related decision-making for novel oncological treatments. This may require assessments to go beyond the performance of the drug to reflect on system performance and impact. For this to happen there needs to be guidance and direction from the European regulator to combat current disparities in the use of RWE across countries.

Session 3: Clinical decision-making and guidelines

The penultimate session focused on the contribution of RWE to the development of clinical guidelines and decision-making. One of the primary aims of guidelines is to ensure that medical evidence is presented in a standard format that helps healthcare professionals apply that evidence in every day practice in the form of clear and comprehensive recommendations on the prevention, treatment and care of patients with specific conditions and diseases.

Policy-makers and payers are increasingly mandating what clinicians can prescribe, and increasingly using value-based decision making to make these decisions. As a result, clinicians can struggle to gain access to innovative treatments for their patients. There is the potential for RWE in this arena to become part of a quality assessment process to enhance health care provision via the optimisation of clinical guidelines and the development of effective treatment protocols.

RWE has several potential advantages over RCT, which is heavily relied upon in terms of evidence generation for clinical guidelines, in that it can increase understanding of patient outcomes, can support the development of evidence-based personalised medicine by linking Electronic Health Records (EHRs) to genomic data sets, can enable patients to take a more active role in their healthcare and can increase the potential to generate new knowledge at a faster rate (Oyinlola *et al.* 2016).

In this session the three questions used to guide discussion were: (1) *What are the mechanisms by which RWE can inform clinical practice?*; (2) *How can we improve access to and sharing of RWE in clinical practice?* and (3) *What can industry do to support clinical practice through RWE?* Discussions in sessions three and four were not separated by condition area as they were in the first two sessions.

A major avenue for RWE in terms of informing clinical practice is the involvement of the patient. The patient is the underlying consistent factor in any clinical practice and their data should be utilised where possible. This data can be captured in four ways: the patient experience, the group experience, patient validation (i.e. using a survey tool) or registries. PO are a potential platform for the mapping of patient related data, although there can be significant variation between PO in terms of size and experience. They also have a role in streamlining clinical practice in cases where guidelines do not exist.

The use of real-world patient related data has already been put into practice in the UK to obtain evidence of drug use in a normal medical setting where an electronic patient data monitoring system, linking primary care, hospitals and pharmacies, was the key tool for data collection (Neville 2017).

One enduring criticism of RWE is the potential bias introduced. However, in any situation where all parties have a vested interest in the results bias can be present. In RCTs data is recorded by independent observers, but these observers are fallible humans and bias can still develop.

Personal clinician experience, or unstructured RWE, can also inform clinical practice and results in treatment variation between clinicians. For example, physicians may be more drawn to follow certain treatment processes or pathways, or use different types of medication based on their personal experience and the experience of the patients they have treated in the past. However, there may be a requirement to change physician behaviour in order to ensure they consistently implement clinical guidelines. Unfortunately, few current guidelines are of high quality, and physicians need to use multiple different guidelines in order to guide treatment decisions for their patients. RWE may play a role in improving this.

RWE has the potential to reduce treatment variability and, in conjunction with clinical guidelines, prompt the use of best practice, or manage clinical behaviour. To get the best out of RWE there needs to be a concerted effort to collect real world data that addresses relevant real world issues, rather than just supporting or reinforcing RCT data, for example, by tracking patient co-morbidities, which may be challenging.

There also needs to be a focus on investigation of potential future opportunities provided by so-called 'big data' to inform clinical practice or decision-making. Ensuring more guidelines are adopted and followed across the board will also

be useful. This can be done by linking commissioning with guideline adoption and developing consequences for situations where guidelines are not followed. For example, if guidelines are not followed it is possible that commissioners will withhold payment.

There were a number of areas, highlighted during discussion, where it was suggested that industry could play a role in supporting better clinical practice via the use of RWE. For example, providing funding for patient data registries to ensure high quality data generation, acting as a link between countries and registry organisations to ensure consistency in data collection quantity and quality. Similarly, industry could do more to facilitate a dialogue between patients and decision makers to enable the drawing of more informed conclusions and the identification of relevant data. Training stakeholders, such as PO, in the importance of RWE and methods for effective collection could build trust and confidence in RWE. Such training may be more relevant in certain countries, or in certain disease areas. Finally, industry could have a role in ongoing patient monitoring to ensure continued data collection with the aim of further supporting and informing clinical guidelines.

Session 4: Patients and outcomes

The final session concentrated on the impact of RWE on patients and outcomes. Despite concerns of some PO representatives present during the discussion related to the focus of some researchers (who could be seen by some to be predominantly focused on publication of their work in high-ranking academic journals as opposed to patient care), the importance of patient-shared decision-making is growing and it is vital to have useful, useable and relevant clinical data available for such decision-making. As part of this, patients need to know more about their own treatment options and be advocates for their conditions.

Two questions guided discussions in this final session: (1) *How can RWE benefit patients through better value and outcomes?*; and (2) *Looking beyond funding what are the opportunities and barriers to patients contributing to RWE generation?*

Patient related data on side effect awareness and management could be vital for improving clinical decision-making. Such data can be collected using a combination of focus groups, surveys, patient forums and online evidence, although there may be a requirement to align systems and databases to support improved data generation via pharmacovigilance.

The consensus during discussion was that patients are becoming more liberal in terms of data ownership and use but there are still issues around access to patient data that can limit evidence generation. For example, some patients may be concerned that allowing their data to be included in patient registries

may mean it will be seen by employers. Mitigating these issues, by ensuring patients understand issues around data confidentiality, may increase their willingness to be involved in data collection. It is also vital that patients are given the tools necessary for them to understand the HTA process as well as possible. Understanding resource limitations and the methods by which the HTA process is used for effective allocation may 'activate' them to participate in RWE related research and data collection. Engagement in the process already happens in certain countries – in the UK patients must be represented on decision-making committees for publicly funded grants – but this is by no means commonplace.

There may also be a lack of interest in research involvement as far as patients are concerned. This lack of interest could be due to their naivety in terms of the potential usefulness of RWE in decision-making. Overcoming this issue may require training and education of patients to increase the understanding of their role in RWE and to help contextualise the overall role of RWE. Such training could be supplied by PO, to inform patients on why RWE is needed and what tools can and should be used to generate data and improve outcomes.

There are some issues at the PO level that may need to be addressed in order for training courses to have an impact. For example, some PO are highly engaged at the EU level but are not always supported by a local affiliate that is easily accessible for all patients - there are at least twenty oncology PO within the EU but only a few individuals within them are actively engaged, and only at the EU level. There is also significant variation in the quality of PO, both between and within countries, and patient willingness to engage with PO differs significantly across disease areas. Only 10-15% of patients contact a PO and motivation for joining can range from support in disease management to supporting research activities. An improved PO impact, on a national level and EU wide, both politically and in the research arena, is vital if patients are to become more engaged in the collection and use of RWE.

The role of industry

The concluding session of the expert meeting focused on the role of industry in enhancing the RWE strategy. Output from the initial meeting held in June 2016 suggested that there were three areas to focus on '*Becoming the leader*'; '*Developing the data*'; and '*Creating the community*'. In the current meeting, KOL could see a role for industry in three broadly similar areas.

Leadership through action

Companies could develop new commercial models, incorporating RWE collection to ensure sufficient data levels. They could also work towards improving data quantity by supporting registry development and completion by supplying

incentives and funding. Facilitating training and support in RWE for patients and PO and facilitating communication between RWE stakeholders, such as patients and decision-makers, would also be beneficial in order to ensure that all stakeholders understand the requirements of RWE, and the importance of its use.

They should also ensure that all global activities are followed through at affiliate level and should explore opportunities around the use of 'big data' – the name given to large of complex sets of data that meet four criteria (volume, velocity, variety and veracity).

Whatever role they play it is vital that the RWE research pillars of transparency, robustness and non-bias are upheld.

Developing credible data

Whilst ensuring data quantity is crucial, it is vital that this data is fit for purpose. There is potential for a disconnect between the generation, interpretation and use of RWE which can limit the benefit that it can provide. Improvement in IT and data capture infrastructure may help build the credibility of RWE. There is also the requirement to create legitimacy by identifying the specific purpose of RWE to ensure collection is fit for purpose. Data requirements may be different if it is being used for commissioning decisions, reimbursement decisions, licensing decisions or clinical decisions.

Credible RWE could be used to validate extrapolation and support modelling, could serve to reduce variability in practice, can enhance early licensing and conditional reimbursement and could be used to extend RCTs in situations where longer-term outcomes are to be measured.

Growing the community

Including PO, and patients, in the RWE 'community', and involving them in data collection, is vital as they are significant stakeholders in the RWE arena. There would be significant benefit from bringing both patients and experts, whether that is payers, clinicians, health insurers or academics, together to learn from each other and to work towards better articulating the social benefits of RWE and better communicating the benefits of participating in RWE studies to patients across the EU. Acting as a community in such a way may alleviate any burdens associated with registry completion. Finally, developing an RWE Guidelines Group may promote consistency in RWE collection.

Concluding remarks

Once again, discussions with European-wide RWE experts further developed our understanding of the role of RWE across the EU. There is no doubt that whilst RWE is at an early stage, the associated benefits are becoming more relevant. However, in order to benefit fully from all that RWE has to offer, we require a good quality, well-organised system for data generation, interpretation and use. For this to happen we need to develop realistic ideas of what can be done with RWE, as well as the associated financial burden. There is a need for strategic work on the differing RWE requirements of different disease areas. For example, in the rare disease arena, RWE may have a role in licensing based decisions; however, it is likely that RWE will not influence licensing decisions for either chronic disease or oncology. There will need to be a multi-stakeholder approach at the EU level, with collaboration between national and supranational organisations and reimbursement agencies, manufacturers and PO, alongside communication of the importance of RWE to patients, particularly those suffering from chronic conditions.

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The authors would like to acknowledge F. Hoffman-La Roche AG for support of this project.

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DOI: 10.21953/LSE.RO.77037. This can be resolved as a URL: <http://dx.doi.org/10.21953/LSE.RO.77037>