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Expert guidance on target product profile development for AMR diagnostic tests

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ABSTRACT

Diagnostics are widely considered crucial in the fight against antimicrobial resistance (AMR), which is expected to kill 10 million people annually by 2030. Nevertheless, there remains a substantial gap between the need for AMR diagnostics versus their development and implementation. To help address this problem, target product profiles (TPP) have been developed to focus developers' attention on the key aspects of AMR diagnostic tests. However, during discussion between a multisectoral working group of 51 international experts from industry, academia and healthcare, it was noted that specific AMR-related TPPs could be extended by incorporating the interdependencies between the key characteristics associated with the development of such TPPs. Subsequently, the working group identified 46 characteristics associated with six main categories (ie, Intended Use, Diagnostic Question, Test Description, Assay Protocol, Performance and Commercial). The interdependencies of these characteristics were then identified and mapped against each other to generate new insights for use by stakeholders. Specifically, it may not be possible for diagnostics developers to achieve all of the recommendations in every category of a TPP and this publication indicates how prioritising specific TPP characteristics during diagnostics development may influence (or not) a range of other TPP characteristics associated with the diagnostic. The use of such guidance, in conjunction with specific TPPs, could lead to more efficient AMR diagnostics development.

SUMMARY BOX

⇒ The growing challenge of antimicrobial resistance (AMR) requires novel diagnostic solutions, for example via the increasing development and use of rapid diagnostics being promoted in multiple strategic initiatives and policy interventions globally.

⇒ One of the major barriers in AMR diagnostics is the large gap between the need for diagnostics versus their development and implementation. In this respect, accessible Target Product Profiles (TPPs) for innovators, contain information that can help them to create diagnostics that are effectively adopted and implemented into end users' environments.

⇒ The Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) Transnational Working Group 'Antimicrobial Resistance - Rapid Diagnostic Test' (AMR-RDT) generated a guidance document for AMR TPP development.

⇒ This guidance takes into account 46 essential characteristics that are grouped into 6 main categories, including the interdependences between these characteristics. The guidance allows potential prioritisation of TPP characteristics during AMR diagnostics development, adding substantial value for academic and business stakeholders involved in AMR diagnostics development, as well as for AMR policy makers.

BACKGROUND

The development and implementation of rapid diagnostics for infectious diseases could reduce time-to-result, improve patient management decisions, help select appropriate therapies, facilitate streamlining during clinical trials and assist in the development and prescription of narrow spectrum antibiotics. Such tests could offer also evidence-based (instead of symptom-based) results that influence clinician decision-making regarding which antibiotics to include or exclude during patient treatment. Molecular methods, automated systems, innovative sampling approaches are all components supporting AMR diagnostics. As an example, 800 million users of a diagnostic tool that discriminates bacterial versus other infections in primary care are expected in 2040.[1] While rapid diagnostics are widely considered a top priority tool to combat the global threat of AMR,[2] there is still a large gap between the need for diagnostics versus their development

and implementation.[3 4] In this respect, a Joint Programming Initiative on Antimicrobial Resistance (JPIAMR)-funded multisectoral working group (AMR-RDT) was established. The working group comprised 51 international experts from industry, academia/research, public health and non-profit/non-governmental organisations (online supplemental table S1). One of the subjects discussed was the potential improvement of the content and structure of specific target product profiles (TPP) that are used during the development of diagnostic tests for AMR prevention and diagnosis.

TPPs are strategic documents that are widely used to define diagnostics development and are generated via scoping, drafting, consensus building and updating steps.[5 6] TPPs comprise lists of characteristics together with minimum acceptable or optimal values that are intended to guide research and development efforts for new diagnostics. They help to ensure that newly developed diagnostics meet application, performance, user, economic and regulatory requirements.[5] These characteristics are often listed with quantitative minimum (acceptable or required) and optimal (desirable) values.

The importance of TPPs has previously been emphasised by Murtagh *et al*, who stated that diagnostics developers value the existence of TPPs, as they provide structured and specific guidance for the development of novel technological diagnostics.[7] Moreover, developing a diagnostic test according to a TPP recommendation could potentially help its Health Technology Assessment, while potentially accelerating time-to-market, acceptability, adoption and implementation,[8] since the development was done based on a consensus-derived use case-specific TPP document.

There are three main types of bodies initiating TPPs, namely (1) industry, (2) public bodies/NGOs and (3) regulatory agencies such as the US Food and Drug Administration (FDA).[9] We focus on the first two categories and we believe that our findings are applicable to both; the latter have been applied (mostly) in the field of pharmaceuticals and are not always one-to-one transferable to diagnostic tests. In the case of industry-led TPP initiatives, companies usually use market research, business development strategies and scientific due diligence to analyse user needs.[10] In the case of public bodies/NGO-led TPPs, several examples are available.[11–16] As an example, guided by a landscape analysis and technical assessment of potential gaps, the WHO developed and published in 2020 AMR-related TPPs for quite specific/narrow purposes, namely (1) a multiplex platform for identification and resistance/antimicrobial susceptibility testing of prioritised bacterial pathogens at level 2 healthcare facilities, and (2) a platform to detect phenotypic antimicrobial susceptibility of prioritised bacterial pathogens to facilitate antibiotic stewardship at level 2 and ideally also level 1 healthcare facilities. Additionally, a WHO directory lists several TPPs for diagnostic products[17] (outside the AMR field), while other non-profit organisations such as UNICEF (eg, for Yellow Fever and Zika viruses, Diagnostic Aid for Acute Respiratory Infection and others),[18] PATH (eg, for malaria, trachoma and neglected tropical diseases)[19–21] and the Foundation for Innovative New Diagnostics (FIND) (sometimes in cooperation with the WHO),[16 22 23] have also developed diagnostics-related TPPs. However, the development of TPPs for medical diagnostics is not per se standardised, with a systematic review by Cocco *et al*[5] indicating four potential limitations to current TPP development, namely (1) subjectivity of input sources; (2) poor transparency in methodology reporting; (3) clinical utility and (4) cost-effectiveness. It was also found that interdependencies between test characteristics are usually overlooked within TPPs to date.[6] Furthermore, Murtagh *et al* utilised TPP experience gained from the WHO initiative for point-of-care testing for sexually transmitted infections to state that 'it would be useful to prioritise each performance/operational characteristic of the test and to provide a rationale as to why certain characteristics are considered important',[7] which is indeed missing from the current state-of-the-art of TPPs.

The aim of this publication is to present guidance on the context (external factors that may influence a particular characteristic) and interdependencies (connections between different characteristics) of AMR TPP characteristics, with the intention of guiding relevant stakeholders to prioritise the most appropriate TPP characteristics for their particular diagnostic and to appreciate how placing a priority on a single TPP characteristic may directly impact on several other important TPP characteristics.

JPIAMR AMR-RDT WORKING GROUP AND APPROACH

In 2016, the JPIAMR provided funding to selected networks to 'enhance resource alignment and maximise existing and future efforts to combat AMR by pushing forward the conceptualisation of ideas'. One of the funded networks was the 'Rapid Diagnostics Test' (AMR-RDT) working group. Candidates for this working group were experts recruited (via email) by its coordinator (Prof. Till T Bachmann) and by suggestions made by existing members of the AMR-RDT group. This was based on their fields of expertise, type of entity that they work, country of residence/work and gender. Previous cooperation and personal communications between members allowed the broad participation of 51 members, forming a single focus group, including 29/51 (57%) diagnostic innovators established at research/academic entities, 10/51 (20%) companies, 8/51 (16%) non-profit/non-governmental organisations (NGOs)/associations and 4/51 (8%) public health bodies. More details of the composition of the working group can be found in online supplemental table S1. The working group was funded for 12 months from 1 January to 31 December 2017. The kick-off meeting took place physically in Brussels, Belgium on 1 February 2017 with regular meetings taking place electronically once per month and towards the end once per 2 weeks. The final physical meeting

took place in Brussels, Belgium on February 2018. The working group remained connected via virtual meetings and email and ensured that the reported findings remained up to date for this publication.

With respect to the current publication, the experts' opinions were gathered via emails and in real-time during the consultations and data was added to Microsoft Office (Excel, Word files). The 'Essential Qualitative Information' including, 'Characteristic', 'Qualitative Explanation', 'Examples of External Influencing Factors' and 'Influencing Characteristics' for AMR diagnostic test TPP are shown in online supplemental table S2. This qualitative data was converted to quantitative by attributing the numerical value '1' when the working group judged that an interdependency between two characteristics occurred (online supplemental table S3). This quantitative data was then analysed using the Cytoscape open source software platform for visualising complex networks[24] in order to acquire the AMR TPP interaction network diagram shown in figure 1. Further details are available in the figure legend.

The current publication utilised scoping, drafting and consensus-building within the JPIAMR AMR-RDT working group to develop the presented information. Once published, stakeholder interest and comment should allow regular updating of the information presented.

The limitations of the current study include the fact that more than half of the working group participants originated from EU/EEA with few representatives from LMICs, where the characteristic *Retail price* may be most important. Nevertheless, the authors feel that the working group included a good representation of expertise from different AMR sectors and would not expect major differences in the interdependencies if a more diverse working group would have been recruited. Also,

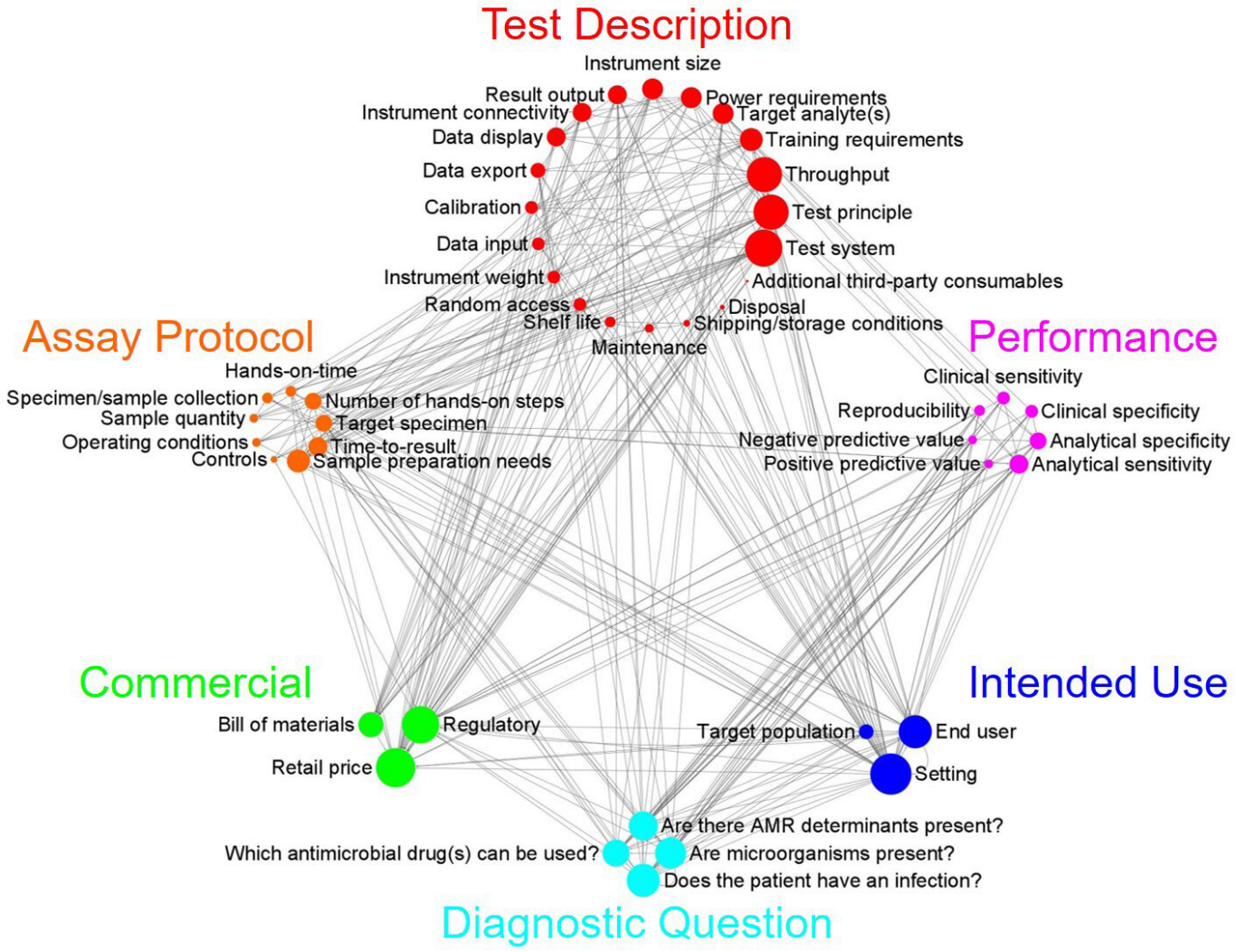

Figure 1 Target product profile Interaction Network Diagram. Lines indicate the presence of an interaction between the different characteristics. Characteristics are shown in black text and are grouped into six different categories, marked in coloured text (refer also to online supplemental table S2). Each characteristic is accompanied by a node (circle). The node size represents the number of interactions that this characteristic is involved with (online supplemental table S3), meaning that the more the lines connected to a node, the bigger the node. For absolute quantification of how many connections are related to each characteristic (node), please refer to online supplemental table S3. AMR, antimicrobial resistance.

it should be noted that this publication is not intended to create 'one more TPP', nor to be a systematic review or landscape analysis of TPPs like other studies.[5 25] Instead, it was based on expert opinions and background expertise of the JPIAMR AMR-RDT working group, through discussions and without the distribution of dedicated or standardised questionnaires or surveys. Although there may be slight differences in the characteristics and their categories terminology used in this publication compared with previous ones, this is not unusual for TPP-related documents,[6] especially as our aim was not to keep the same terminology, but to provide as complete and representative a set of characteristics as possible.

TPP CHARACTERISTICS AND INTERDEPENDENCIES

The authors provide 46 key characteristics and their interdependencies. These characteristics are grouped into six main categories, as shown in figure 1, and the first column of online supplemental table S2. Of these categories: (1) 'Intended Use' includes three key characteristics that essentially render each TPP, case-specific; (2) 'Diagnostic Question' includes four characteristics that are exactly the diagnostic questions that AMR diagnostics developers will have to address; (3) 'Test Description' includes 20 characteristics that are related to the instrument, the generated data and storage/shelf life; (4) 'Assay Protocol' includes nine characteristics that refer to the specimen properties, quantity, hands-on requirements, controls and operating conditions; (5) 'Performance' contains seven characteristics that define the analytical, clinical sensitivity and specificity, positive/negative predictive value and reproducibility and (6) 'Commercial' gathers three characteristics relevant to price and regulatory issues. Such TPP characteristics will also have to be met by developers in evaluation studies for the process of commercialisation of their tests.[26]

Contrary to specific use-case TPPs (that list quantitative ranges and values for each characteristic) and with a broad audience of AMR specialists in mind, we provide a qualitative explanation of characteristics (second column in online supplemental table S2), allowing TPP developers to assign their own context-specific value to characteristics dependent on their own use-case AMR TPP.

We also identified and describe the external factors (third column in online supplemental table S2) that may influence the quantitative ranges of each characteristic. Such information on external factors is typically not found in TPPs. Examples of such key external factors are as follows: (1) intended or available treatment or management option; (2) target markets; (3) accessibility; (4) the expected frequency of use (of the diagnostic test); (5) competitor performance and (6) business model and health economics—the latter being in line with earlier studies that recommend an early economic evaluation of diagnostic technologies[27 28] and integration of such evaluation into TPP development for medical tests.[21] Notably, there were no characteristics with zero external influencing factors.

All characteristics (first column of online supplemental table S2) had at least one influencing characteristic (fourth column of online supplemental table S2) and three characteristics were influenced by >10 other characteristics: (1) *Retail price* by 15; (2) *Training requirements* by 12 and (3) *Bill of materials* by 12. On the other hand, the characteristics that were least influenced by other characteristics were as follows: (1) *Additional third-party consumables* by 1; (2) *Are microorganisms present* by 2 and (3) *Setting* by 2.

Forty out of 46 characteristics act as 'influencing characteristics' (thereby defining interdependencies). The most influential characteristics are the *Setting*, *Test system*, *Test principle* and *Does the patient have an infection*, which have interdependencies with 39, 20 and (the latter two) with 18 of the 46 characteristics, respectively. The six that do not act as influencing characteristics (and do not appear in the fourth column of online supplemental table S2) are: *Disposal, Maintenance, Negative Predictive Value, Positive Predictive Value, Training requirements* and *Reproducibility*.

At the 'category level', the number of connections are as follows: (1) 'Intended Use' with 14; (2) 'Diagnostic Question' with 11; (3) 'Test Description' with 128; (4) 'Assay Protocol' with 53; (5) 'Performance' with 51 and (6) 'Commercial' with 37. All of the aforementioned quantitative information is summarised in figure 2 and provided in online supplemental table S3.

RELATIONSHIPS BETWEEN INTERDEPENDENCIES

Figure 1 and online supplemental tables 2 and 3 show that each TPP characteristic (represented with a node in figure 1) is potentially interdependent with other characteristics and provides some measure of the 'quantity' of that relationship (ie, the number of connections between characteristics). For TPP users, this means that placing priorities on a single TPP characteristic may have an impact on an entire range of other TPP characteristics.

In more detail, the categories 'Test Description' and 'Assay Protocol' are closely linked, as most diagnostics innovators would expect. More surprisingly, only two of the 'Test Description' nodes (*Test principle* and *Target analytes*) have connections with the 'Performance' category. Instead, strong links exist between the 'Performance' category and 'Commercial' and 'Intended Use'. This highlights the strong influence of commercial drivers and the desired application of the AMR-related diagnostic test. Similarly, how well a test must perform ('Performance') is most prominently driven by what the end-user wants to know when using the test ('Diagnostic Question'). It is also revealing to see the dominance of *Setting* (large node) over *End user* and *Target population*, which underpins the importance of the location of the target population over who is doing or receiving the test. Other highly influential characteristics in the network

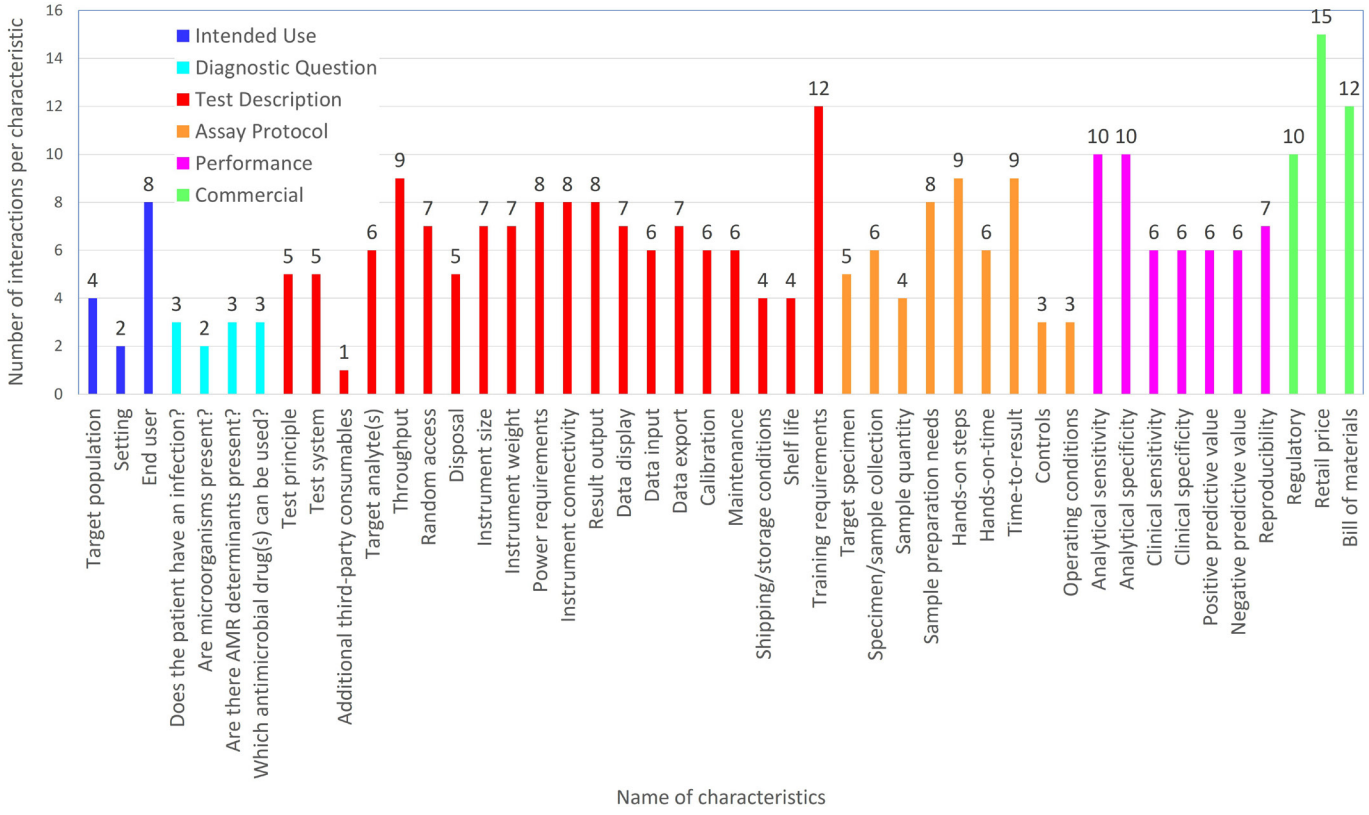

Figure 2 Bar diagram depicting the number of interconnections of each of the 46 identified key TPP characteristics that were associated with six different colour coded categories (see also figure 1). TPP, target product profile.

are *Retail price*, *Regulatory*, *Test system*, *Test principle* and *Throughput*. Interestingly, *Test system* is not connected to the 'Performance' and 'Diagnostic Question' categories. However, the *Test principle* is indeed connected with the 'Performance' category. This makes sense, as the analytical sensitivity is generally higher with a molecular than a phenotypic assay. Thus, the 'Diagnostic Question' defines the *Test system* and *Test principle* via the *Setting* and *End user*. For the influential 'Commercial' category, only *Regulatory* has links with the 'Diagnostic Question'. Finally, the most decisive cost per test aspect is covered by *Bill of materials* (almost entirely linked to 'Test Description' category) and *Retail price* which has wider connections to all categories except 'Diagnostic Question'.

Contrary to use case-specific TPPs, the novelty and highlight of this guidance lies in the fact that TPP development is approached from a general rather than a use case-specific perspective. We provide 46 key characteristics, as well as external influencing factors and guidance on their interdependencies between characteristics that can help diagnostic developers to approach AMR TPPs in a more structured and priority-driven manner. The main guidance is shown in the qualitative schematic representation (figure 1) and the quantitative correlation (figure 2) of interdependencies between characteristics. The importance of the publication lies in the fact that the concept of interconnected AMR TPP characteristics will offer added value to AMR diagnostic product developers, helping them prioritise the interactions/nodes that are likely to have the greatest impact on the final AMR diagnostic product. It also allows such developers to discover if, when or how a change in one test characteristic may subsequently affect other test characteristics.

CONCLUSION

The importance of this study lies in the interdependencies that have been identified between different characteristics associated with AMR diagnostic TPPs. Such interactions may not yet be evident when following the standard TPPs currently available, meaning that this information will be useful in helping AMR diagnostics developers to prioritise the different TPP characteristics associated with their own particular AMR diagnostic and provide a basis to explain why certain characteristics are considered important. The guidance is expected to be applied and used by diverse AMR stakeholders, including: (1) developers of use case-specific TPPs, for example, companies, or non-commercial bodies such as academic, research experts, non-profit/non-governmental organisations, associations, etc.; (2) developers of AMR diagnostic tests (in fields ranging from (bio)chemistry, medicine, engineering and information technology, etc) and (3) health technology assessment agencies, reimbursement bodies and insurance companies.

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