DOI 10.24144/2077-6594.3.2020.208607
УДК 615+661.12:006

Gorbenko O.[1], Williams M.[2]

Looking for optimal standards, criteria and KPIs of patient centricity across the biopharma industry: an overview of existing frameworks and conceptual models (Part 2)

[1]ViiV Healthcare, United Kingdom
[2]Executive Insight, Switzerland

algostand@gmail.com, m.williams@executiveinsight.ch

Горбенко О., Вільямс М.
У пошуку оптимальних стандартів, критеріїв та ключових індикаторів виконання завдань з пацієнт-орієнтованості у сфері біофармацевтичної індустрії: огляд рамкових платформ та концептуальних моделей (частина 2)
ViiV Healthcare, Executive Insight

Горбенко А., Вильямс М.
В поиске оптимальных стандартов, критериев и ключевых индикаторов выполнения заданий по пациент-ориентированности в сфере биофармацевтической индустрии: обзор существующих рамочных платформ и концептуальных моделей (часть 2)
ViiV Healthcare, Executive Insight

Introduction

As a part of our taskforce aimed to comprehensively analyse the selected 12 patient centricity frameworks and conceptual models, we planned to evaluate their implementation potential and possible adoption of their key elements by the biopharmaceutical industry. Alongside such characteristics as frameworks'/models' key objectives, authorship (which stakeholders developed and proposed them, whether patient representatives were involved or not), targeted stakeholders, targeted medicine lifecycle stage or industry/healthcare operations, proposed key elements criteria, standards, KPIs or other indicators, – this analysis should navigate industry representatives in the search and defining optimal measurements of success within corporate patient centricity.

The following frameworks and conceptual models as well as their key elements were analysed and described in the part 1 of our work (Tab. 1).

Table 1. **Analysed frameworks/conceptual models and their key elements**

	Framework or conceptual model	Proposed key elements: criteria, standards, KPIs or other indicators
1	PatientView (hereafter PatientView) [1]	1. Authenticity 2. Support and services 3. Transparency 4. Involvement in R&D 5. Quality product information 6. Patient Group relations 7. Patient safety 8. Equitable access 9. Valued products
2	PFMD (Patient Focused Medicine Development) meta-framework (hereafter PFMD) [3]	1. Shared purpose 2. Respect and accessibility 3. Representativeness of stakeholders 4. Roles and responsibilities 5. Capacity and capabilities for engagement 6. Transparency of communication and documentation 7. Continuity and sustainability
3	CTTI (Clinical Trial Transformation Initiative, hereafter CTTI) [2]	The key recommendations are: • Early involvement • Comprehensiveness

		• Mutual transparency and confidentiality • Diversity and representativeness
4	NexGen/OxyGen (hereafter NextGen/OxyGen) patient centricity frameworks (Eyeforphrama 2017) [8]	Key elements of the NexGen assessment industry-standard framework on patient centricity: 1. Innovation 2. Vision 3. Governance 4. Insights 5. Activities 6. Sharing 7. Evaluation OxyGen is a checklist to evaluate patient-centred care by pharma
5	National Health Council (NHC) Framework (hereafter NHC) [6]	• Focus on meaningfulness and the related criteria/questions to assess engagement (What? Who? When? How? Expected impact? Actual Impact?) • Criteria of best practice examples of patient engagement
6	PFDD Conceptual Framework or M-CERSI (University of Maryland Centre of Excellence in Regulatory Science and Innovation; hereafter PFDD-M-CERSI) [15]	Engagement level can be evaluated by the gradual criteria: • Patient role • Continuity • Meaningfulness • Representativeness • Temporality
7	KINAPSE conceptual model for managing performance in patient centricity by pharma (hereafter KINAPSE) [5]	External KPI categories include: • Patient outcomes (including patient activation) • Patient experience • Access and adherence (external process) Internal KPI categories include: • Strategy • Capability • Process (internal)
8	Patient Centred Outcomes Research Institute (PCORI) engagement rubric (hereafter PCORI) [9,10]	• Reciprocal relationships • Co-learning • Transparency, honesty and trust • Partnerships throughout study planning, conduct and dissemination • Supported by real-world examples
9	National Institute for Health Research (UK NIHR) INVOLVE (hereafter INVOLVE) [7]	Key elements of co-producing a research project: • Sharing of power • Reciprocity • Respecting and valuing the knowledge of all those working together on the research • Including all perspectives and skills • Building and maintaining relationships Respectively, the standards are: 1. Inclusive opportunities 2. Working together 3. Support and learning 4. Communications 5. Impact 6. Governance
10	Perfetto et al, Framework (hereafter Perfetto) [12]	• Validity, reliability and maturity of the science • Communication of the science • Applicability • Economic drivers • Integration into guidelines
11	FastCures Value Framework (hereafter FastCures) [4]	5 domains of patient value and technical criteria: • Patient preferences

		• Patient-centred outcomes • Patient and Family costs • Quality and applicability of evidence • Usability and transparency
12	National Voices, UK (hereafter National Voices) [11,14]	• Products/services • Innovation (in partnership with patients) • Workplace • Citizenship (responsibility, ethics, transparency) • Leadership • Performance (perform well for all stakeholders)

Objectives

- To analyse the implementation potential of the selected frameworks and conceptual models, possible adoption of their key elements by the biopharmaceutical industry and patient community as unified standards, criteria or KPIs;
- To develop recommendations for the industry on selection and operational adoption of the most feasible patient centricity frameworks and/or conceptual models taking into consideration the results presented in the part 1.

Methods

The modified implementation outcomes criteria (IOCs) were used to evaluate the potential for successful implementation/adoption of the selected conceptual models and frameworks alongside adoption opportunity of the proposed key elements: patient centricity criteria, standards, KPIs and other impact indicators across the industry. In 2010 Proctor E. et al. substantiated the concept of implementation outcomes across healthcare with the aim to conceptualize, unify and evaluate successful implementation of several technologies/interventions [13]. A working 'taxonomy' was proposed, consisting of 8 IOCs with the definitions: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration/coverage and sustainability. This formed a robust basis for the assessment of implementation/adoption success or potential success, either prospectively (for planned interventions) or retrospectively (for already implemented interventions). The original criteria were modified for the qualitative assessment of the selected conceptual models and frameworks (Tab. 2), with the focus on 3 key IOC: comprehensiveness (formerly penetration/ coverage), appropriateness (as the original) and potential adoption/implementation made up of 6 sub-criteria (modified based on 'adoption').

Table 2. **Modified and original Implementation Outcomes Criteria**

Implementation outcomes criteria (IOC) for frameworks or conceptual models	**Original description (E. Proctor, et al. 2010 [44])**	**Explanation/how it can be used for the assessment**
1. Comprehensiveness	The original criterion is **"Penetration/ coverage"** which reflects the level of institutionalization	• Coverage of the medicine lifecycle/ development continuum (MDC) phase(s) • Coverage of the care continuum phase(s) • Coverage of targeted stakeholder groups, in particular, patients
2. Appropriateness	**Appropriateness;** Perceived fit; relevance; compatibility; suitability; usefulness; practicability	• How relevant the proposed standards/ elements/parameters to the industry and how could they be aligned to the corporate strategy/objectives
3. Potential adoption/ implementation with the following sub-criteria: o Feasibility o Fidelity o Measurability	**Adoption;** uptake; utilization; initial implementation; intention to try **Feasibility;** Actual fit or utility; suitability for everyday use **Fidelity**; Delivered as intended; adherence; integrity; quality of program delivery No prototype	• Extent to which the proposed standards/ elements/parameters can be implemented by industry functions, at the several levels (within existing roles/responsibilities & capabilities) • Extent to which the proposed standards/ elements/parameters could be implemented by the industry as originally designed/intended • Extent to which the proposed standards/ elements/parameters could be assessed using KPIs following implementation

○ Implementation resources	**Implementation costs;** Marginal cost; cost-effectiveness; cost-benefit; practicability	• Resources potentially required for implementation of the standards/elements/ parameters: ○ Personnel/time required to implement ○ Financial cost ○ Technical/digital and other infrastructural resources
○ Sustainability	**Sustainability;** Maintenance; continuation; durability; incorporation; integration; institutionalization; sustained use; routinization	• Extent to which the proposed standards/ elements/parameters can be routinely executed by industry (become standard industry practice in the long-term upon pilot stage)
○ Scalability	No prototype	• Extent to which the standards/elements/ parameters can be systematically applied by: ○ organisations with different business models/operations ○ organisations with different size/turnover ○ organisations with different capacities and resources ○ organisations in several countries worldwide ○ organisations focused on several therapy areas

The modifications of the original concept were prompted by broader consideration of changes to be implemented across the biopharmaceutical industry and their focus on such outcomes as improved business processes, operations and corporate culture shifting rather than outcomes from clinical or non-clinical interventions within healthcare systems, which the original concept was proposed for. The four original IOC appropriateness, feasibility, fidelity and sustainability were retained; the two original criteria, penetration/coverage and implementation costs were adapted and referred to as comprehensiveness and implementation resources respectively; adoption was adapted to potential adoption/implementation and referred to as a consolidated criterion with six sub-criteria of feasibility, fidelity, measurability, implementation resources, sustainability and scalability; two newly proposed criteria, measurability and scalability were added under the consolidated criterion of potential adoption/implementation and the original criterion acceptability was perceived as inappropriate for the assessment due to the specific nature of such novel research (which has not been conducted before). Overall, the modifications allowed the authors to assess the selected patient centricity frameworks and conceptual models to be adopted/implemented across the biopharmaceutical industry based on refined IOC specific to the research question. The outputs of the assessment against the modified IOCs were summarised in table 3.

A 5-grade system was used to evaluate the selected frameworks and the extent to which the proposed standards/ elements/parameters can potentially be implemented by the industry: from 1 (lowest potential) to 5 (highest potential). More specifically, the comprehensiveness were evaluated as 5 (the most comprehensive) and 1 (the least comprehensive); the appropriateness – as 5 (the most appropriate and high potential to be aligned with corporate strategy and objectives) and 1 (the least appropriate and no potential to be aligned with corporate strategy and objectives); the feasibility – as 5 (the most feasible and implementable by the industry functions) and 1 (the least feasible and implementable by the industry functions); the fidelity – as 5 (can potentially be implemented as originally designed/proposed) and 1 (cannot be implemented as originally designed); the measurability – as 5 (can potentially be measurable through tangible KPIs/metrics) and 1 (cannot be measurable through KPIs/metrics); the implementation resources – as 5 (the lowest resources demand) and 1 (the highest resources demand); the sustainability – as 5 (the most sustainable over a long period of time) and 1 (the least sustainable/not sustainable over a long period of time); scalability – as 5 (the most scalable and highly replicable by several organisations and groups) and 1 (the least scalable and not replicable by several organisations and groups). The evaluation was conducted through open authors' discussion around each framework/conceptual model and sequential consideration of possible implementation scenarios against each IOC. The outputs and opinions from the previous internal (within the company) and external (PFMD workstreams, other workshops and conferences) discussions were taken into consideration and authors have finally agreed their opinion regarding each framework or conceptual model.

Practical recommendations for the possible implementation and operational adoption of the analysed frameworks and conceptual models were developed.

Results

The results of the framework and conceptual model analysis against the modified IOCs are consolidated in Tab. 3; the proposed key elements of each framework or conceptual model were assessed in terms of their comprehensiveness (penetration/coverage), appropriateness for potential adoption/ implementation by the industry and extent to which they meet the sub-criteria of the adoption IOC. The findings are discussed in the following section.

Table 3. **The results of the frameworks and conceptual model evaluation against the modified IOCs**

Implementation outcomes criteria (IOC) for frameworks or conceptual models	PatientView	PFMD	CTTI	NexGen/OxyGen	NHC	PFDD-M-CERSI	KINAPSE	PCORI	INVOLVE	Perfetto	FastCures	National Voices
1. Comprehensiveness	5	5	4	3	4	4	4	4	5	2	**3**	**3**
2. Appropriateness	5	3	4	4	3	3	5	3	3	4	**4**	**4**
3. Potential adoption/ implementation with the following sub-criteria:												
a. Feasibility	4	4	3	3	5	3	4	3	3	3	**4**	**2**
b. Fidelity	3	2	1	1	2	1	2	1	1	1	**1**	**1**
c. Measurability	4	3	2	3	3	3	4	2	3	3	**3**	**2**
d. Implementation resources	1	2	4	3	1	3	1	4	2	2	**1**	**2**
e. Sustainability	4	5	5	3	4	4	4	4	5	4	**4**	**4**
f. Scalability	4	4	3	3	4	3	5	3	4	3	**4**	**5**
Total score	**30**	**28**	**26**	**23**	**26**	**24**	**29**	**24**	**26**	**22**	**24**	**23**
Mean score	**3,75**	**3,50**	**3,25**	**2,88**	**3,25**	**3,00**	**3,63**	**3,00**	**3,25**	**2,75**	**3,00**	**2,88**
Ranking	**1st**	**3rd**	**4th**	**6th**	**4th**	**5th**	**2nd**	**5th**	**4th**	**7th**	**5th**	**6th**

Evaluation key: comprehensiveness: 5 (the most comprehensive) and 1 (the least comprehensive); appropriateness: 5 (the most appropriate and high potential to be aligned with corporate strategy and objectives) and 1 (the least appropriate and no potential to be aligned with corporate strategy and objectives); feasibility: 5 (the most feasible and implementable by the industry functions) and 1 (the least feasible and implementable by the industry functions); fidelity: 5 (can potentially be implemented as originally designed/proposed) and 1 (cannot be implemented as originally designed); measurability: 5 (can potentially be measurable through tangible KPIs/metrics) and 1 (cannot be measurable through KPIs/metrics); implementation resources: 5 (the lowest resources demand) and 1 (the highest resources demand); sustainability: 5 (the most sustainable over a long period of time) and 1 (the least sustainable/not sustainable over a long period of time); scalability: 5 (the most scalable and highly replicable by several organisations and groups) and 1 (the least scalable and not replicable by several organisations and groups).

Discussion

From a practical point of view, the critical question is to what extent the proposed frameworks and conceptual models are implementable/adoptable by organisations of the biopharmaceutical industry, particularly by their business units and corporate functions. Such a strict requirement on tangibility must be addressed first, however, there is greater complexity when answering this question and whether such implementation steps would be supported by patients and patient organisations the industry works with. Taking the fact that some of the analysed conceptual models and frameworks are "patient light" in terms of basic input from patient community, there is a common need of continuous consultations and advice from patients and patient organisations throughout the implementation/adoption process. In addition, the industry is represented by several organisations across different geographic areas, therefore a potential for implementation/adoption, resources, needs and requirements varies significantly. The modified IOCs are helpful for this consideration to ensure sequential, balanced and comprehensive modelling.

Comprehensiveness

Comprehensiveness is an IOC which replaces the original Proctor criterion of "Penetration/coverage" and reflects the level of potential institutionalization across the phases of the medicines development continuum (MDC), lifecycle, relevant care continuums as well as coverage of stakeholders. The more unified a framework or conceptual model in terms of patient engagement across several phases of medicines' development and involvement of several stakeholders (multi-stakeholder), the more comprehensive it is. The selected R&D frameworks/conceptual models with the focus on all phases of the MDC could potentially be considered as comprehensive (PFMD, PFDD-M-CERSI, PCORI, INVOLVE, CTTI, NHC) with the known limitations that R&D is only one of the industry functions. The key elements of the INVOLVE and PFMD frameworks may have a broader adoption across the industry going far beyond R&D operations.

In contrast, the selected frameworks/conceptual models targeted to the specific value/care continuums (Perfetto, FastCures) cannot generally be considered as comprehensive. Assessment outputs for the selected industry-oriented frameworks/conceptual models depends on the coverage of the key industry functions, infrastructure and procedures by the proposed elements (KPIs, standards and criteria), therefore PatientView could potentially be considered as one of the most comprehensive frameworks analysed, which highlights the nine attributes of patient centricity for the industry to be potentially driven by almost all functions and business units (patient affairs, market access, external affairs, legal and compliance, human resources, digital/IT, analytics, finances, commercial operations, medical affairs, safety, regulatory affairs, R&D and others). The content analysis has also shown the higher alignment and similarity of those attributes with the key elements of other frameworks/conceptual models. KINAPSE does not consider a functional level but explores a more "environmental" (external/internal) approach for patient-centricity and its holistic measuring as well as key success factors for this. The infrastructural/procedural elements of other industry-oriented frameworks/conceptual models do not fully reflect all aspects of industry functioning, only some aspects are covered in each.

Appropriateness

The evaluation of this IOC addresses the questions on the relevance of the proposed elements to the biopharmaceutical industry and how they could potentially be aligned to corporate strategy and objectives. An important aspect of appropriateness is how likely a conceptual model or framework would be supported by patient communities. As expected, the industry-oriented frameworks and conceptual models developed with consistent input from patient experts PatientView, National Voices) seem to be the most appropriate for implementation/adoption by the industry, whilst the multi-stakeholder, attributable, less specific frameworks are respectively considered as less appropriate. For example, R&D frameworks and conceptual models make recommendations not just to the industry, but also to academic institutions as key research sponsors alongside investigators (investigator-sponsored studies), which explores a more generic approach. Even though such recommendations are targeted to the industry, they do not cover other corporate functions. The selected value-based frameworks (Perfetto and FastCures) could be considered as appropriate and well-aligned to corporate strategy, as more and more organisations are switching their business models from product-centred to value-centred and trying to address unmet patient needs and the growing requirements of value-based HTA. The key element of "Valued products…" and its variations have the highest cross-referencing level among other infrastructural/procedural elements, which reflects its importance for patients. From a functional point of view, it has certain limitations within the industry, as market access and/or health outcomes groups are only accountable for the analysis of medicines value/HTA submissions and development of payer value propositions.

Feasibility

The original IOC of feasibility was modified to evaluate the extent to which the proposed key elements can potentially be implemented by industry functions, at the several levels (within existing roles/responsibilities & capabilities). It is interrelated to the IOC of appropriateness, although with a greater operational connotation. Implementation scenarios and conceptual modelling was used to understand whether the proposed frameworks and their key elements could potentially be adopted by several business units, local/cluster/regional operating companies/representative offices, subsidiaries and global functions. Although the higher graded frameworks and conceptual models, including those more industry-oriented, did not mention any relevance to the dedicated industry function or units (PatientView, PFMD, NHC, KINAPSE, FastCures), their subject-matter elements may be taken into consideration and successfully implemented. For example, almost all corporate structures could potentially be involved in self-evaluation by the proposed 9 PatientView attributes of patient centricity and related standards; the 7 PFMD patient engagement quality criteria could potentially be followed by all roles (individual level) and units (functional level); the generic, simplified checklists and criteria for best practice examples proposed by NHC could potentially help everybody across the industry to make sure their patient engagement activities are meaningful and ethical. KINAPSE framework introduces the fundamental measurement approaches used to monitor patient benefit from healthcare, such as patient activation, patient experience, outcomes, process and volume, which have been adopted for the industry needs. Regardless of functional focus, all levels and structures within industry should run their business following good strategy, appropriately developed capabilities and well-coordinated internal processes, which have been considered by this framework as basic internal KPIs. The key infrastructural/procedural elements of the lower graded frameworks or conceptual models are important for the industry, but they do not reflect the functional specificity and therefore their adoption potential is disputable. For example, there is no clarity on how one could potentially adopt such key elements as performance, workplace, products/services, economic drivers, temporality. The proposed key attributable elements, especially those with higher levels of cross-referencing, have a higher adoption potential and could potentially be considered as theoretical pillars of patient engagement by industry functions. Notably, some frameworks propose feasible parameters for the dedicated functions with detailed practical recommendations: patient affairs/patient centricity, if these exist in a company (NextGen/OxyGen), and global health/health outcomes/implementation science/government affairs, public policy and advocacy (FastCures). However, their broader implementation by other functions seems disputable.

Fidelity

As per the proposed modification, fidelity is an IOC which assess the extent to which the proposed key elements and parameters could potentially be implemented by the industry as originally designed/intended. None of the selected frameworks and conceptual models could potentially be

adopted and implemented in their native format by industry functions without significant modifications because of a lack of focus, low specificity, misaligned terminology, significant heterogeneity, absence of piloting in organisations (except NextGen/OxyGen and PFMD), inconsistency with other developed concepts, methodology bias, intangibility/doubtful tangibility and limited coverage. These reasons are common and more or less applicable to each selected framework or conceptual model. Although, the key elements or general format of some frameworks (PatientView, PFMD, NHC, KINAPSE) could potentially be used as prototypes for further industry-oriented patient engagement frameworks and metrics.

Measurability

Measurability – is a newly proposed IOC for the assessment, which has no prototype in the original IOCs' taxonomy proposed by Proctor E. et al. The measurability IOC defines the extent to which the proposed attributable and infrastructural/procedural key elements – patient engagement standards, criteria or parameters could potentially be assessed using KPIs following implementation by the industry. In other words, it defines whether the implementation/adoption success is measurable and has tangible outputs. The lack of tangibility could be considered as a major obstacle and reason why the proposed frameworks have yet to be implemented by the biopharmaceutical industry. Some of the selected frameworks or conceptual models (PFMD, KINAPSE, PatientView, PFDD-M-CERSI, NHC, Perfetto, FastCures) substantiate KPIs to measure patient centricity, success/outputs from patient engagement activities, patient involvement in several processes, but none of them introduce specific KPIs for the industry that take into consideration functional accountabilities, roles, processes and operations. Several types of the checklists, criteria of best practice examples for patient engagement, requirement to provide a case study as a proof, suggestions/recommendations for KPI development and some generic indicators, like PCOs – are common formats for measuring success, which were proposed by the selected frameworks or conceptual models. The higher the level of details that they contain, the great the opportunity that they provide to develop more specific, tailored KPIs for the industry and the higher their score. For example, PatientView proposes a self-evaluation toolkit for the industry around 9 patient centricity attributes; each attribute has areas to be included to review and deployed checklists with detailed questions under each area, which could potentially be prototypes for specific KPIs. More attributable, but still targeted questions were proposed by PFMD to access any patient engagement activity against 7 quality criteria. Much more simplified checklist and criteria for best practice examples were proposed by NHC. KINAPSE developed a set of recommendations and suggestions for patient centricity KPIs for the industry, whilst specific KPIs have not been developed. OxyGen presents a checklist to evaluate patient-centric care by the industry with disputable perspectives to follow-up implementing more specific KPIs. CTTI recommends the creation of a set of standard metrics to assess the effectiveness of partnerships with patients and the community, however the standards themselves were not defined. Gradual evaluation criteria of good patient engagement were proposed by PFDD-M-CERSI framework, but the way of their practical implementation across the US healthcare system is a subject for further consultations and regulatory decisions (PDUFA VI and 21st Century Cures Act). PCORI recommends using real-world examples of patient engagement throughout the MDC as a proof of tangible outputs. INVOLVE defines the standards on public involvement in research with clear indication whether they are met or not and the "impact" standard has not been supported by any kind of KPIs. The value-based frameworks (FastCures and Perfetto) are mostly oriented to PCOs within healthcare and not specifically for the industry. For example, FastCures introduces the 5 domains of patient value and correspondent technical criteria, including PCO, patient preferences, patient and family costs, which should be assessed through a disease care continuum. Such patient-centric criteria are being widely explored by the industry (health outcomes, R&D and medical affairs within clinical operations), however it is still a question as to whether they could potentially be used as prototypes for more specific outcome-oriented KPIs in other corporate functions and units. Overall, considering the wide diversity of the proposed approaches, above mentioned tangibility issues, medium-low potential for the development of industry-specific KPIs from the proposed key elements and prototypes, there is a clear need for deeper analysis, piloting and consultations to develop tailored and tangible measurements.

Implementation resources

Alongside measurability, the resources required to implement the proposed key elements of patient centricity are under constant scrutiny by industry stakeholders. In contrast with the originally proposed IOC of implementation costs (E. Proctor et al.), the modified IOC contains sub-criteria for the broader evaluation of resources potentially required for the implementation of the attributable and infrastructural/ procedural elements: personnel/capacities, time, financial costs, technical/digital and other facilities/resources. The resources potentially required for the adoption of the selected frameworks and conceptual models vary. The more diversified areas of patient engagement and more prescriptive/specified elements proposed by a framework, the more resources might potentially be required for their implementation. On the other hand, less specific, attributable elements (transparency, capacity and capabilities for engagement, authenticity, roles and responsibilities, diversity and representativeness, continuity and sustainability) may require even higher resource mobilisation within a company, either relevant to a dedicated function (patient affairs/patient centricity), or responsible points of contact across several functions and business units. The development of virtual scenarios, when the proposed elements are implemented across an organisation, may particularly address the questions on how much should be mobilised/used there to deliver a successful patient-centric strategy and undertake the relevant actions. Up to May 2019, the piloting cases are well-known for the two selected frameworks (PatientView and PFMD), therefore the real industry experience could be helpful in terms of evaluation of possible implementation resources. The frameworks/ conceptual models where the PCOs/patient preferences/patient

experience are the key proposed elements (KINAPSE, FastCures) require more resources in terms of effort to collect, track, analyse, interpret findings and finally deploy a strategy. KINAPSE provides clear recommendations on the external and internal process, where the appropriate resource allocation is critical. The elements of "Continuity and sustainability" (PFMD, PFDD-M-CERSI) and "working together"/"building and maintaining relationships"/"patient group relationships" (PatientView, INVOLVE) require even more complexity in resource allocation, which can contribute to long-lasting, efficient partnerships, however, this needs thorough planning and staff, time, financial and other resource mobilisation. Similar considerations are in place when implementing requirements to provide case studies on a regular basis (PCORI engagement rubric, NHC). The patient centricity "evolution ladder" (National Voices) reflects the growing requirements to format and quality of patient engagement by the industry, therefore, the highest level (co-creation, co-development) requires the highest resource mobilisation and performance.

Sustainability

Sustainability is an IOC that refers to the appropriate resources and is interrelated with the previous IOC. The IOC of sustainability defines the extent to which the proposed key elements can be routinely executed by industry in the long term, upon pilot stage. There is an expectation, that well cross-referenced, generic attributable elements are more sustainable, than specific, infrastructural/procedural elements with much higher probability to be replaced/changed/removed/adjusted tailoring the industry needs. Respectively, the frameworks or conceptual models that proposed more attributable elements (PFMD, INVOLVE, CTTI, PFDD-M-CERSI) can potentially be considered as more sustainable. While, for the key infrastructural/procedural elements, the picture is different: focus on valued medicines is cross-referenced in PatientView, FastCures and Perfetto frameworks, therefore they can routinely be used by the industry with some limitations regarding other more specific and less sustainable elements. The frameworks with a limited number of key elements but proposed basic principles of patient engagement (simplified checklists, requirements to provide supportive case-studies – NHC, PCORI) should also be considered as sustainable. Overall, the assessment by the IOC of sustainability has demonstrated higher marks for all selected frameworks and conceptual models, because of better potential for integration, institutionalization and routinization of the proposed key elements.

Scalability

There is an important part of the assessment to define the extent to which the proposed key elements can potentially be applied by several organisations across the biopharmaceutical industry having different business models and operations, size, turnover, resources and capacities, geographic representation and with a focus on several therapeutic/disease areas. This is a new IOC for the assessment, which reflect heterogeneity of organisations and therefore different implementation/adoption potential. Some aspects of potential scalability of the proposed frameworks/ conceptual models have been discussed above in terms of the different implementation resources that companies have available. The more specific/detailed key elements a framework has, the less scalable they are taking diversified needs and expectations of different stakeholders; the similar rule applies to the previous IOC of sustainability. The most common attributable key elements – transparency, reciprocity, diversity and representativeness, meaningfulness, capacity and capabilities for engagement are low-specific and could potentially be followed by several organisations: local, regional or global, originators or generic-oriented, full-cycle manufacturers, wholesalers, R&D- or commercialisation phase oriented etc. The "Valued products and quality product information" element is not specific to the majority of manufacturers and licence holders as well. Alongside the frameworks or conceptual models with the highest cross-referencing and focus on those elements, other frameworks (KINAPSE, National Voices) may potentially be scalable due to the developed recommendations for the industry. The main limitation for the selected multi-targeted R&D frameworks and conceptual models (PFMD, PFDD-M-CERSI, CTTI, PCORI, INVOLVE) is that they may not be applicable for non-R&D (non-full development cycle) organisations, which do not operate throughout the MDC. On the other hand, the frameworks with a particular focus on late development stages, commercialisation and evidence communication (FastCures, Perfetto) may not be applicable for full-cycle R&D organisations.

Conclusions and recommendations

Authors acknowledge some methodology limitations in terms of using IOC which initially were developed for the analysis of implementation potential of several medical technologies within healthcare settings, but not for process improvements and operational excellence across the biopharmaceutical industry. To adjust the existing tool, the IOC were modified and re-defined. There is a first attempt to analyse the frameworks and conceptual models of patient centricity developed over the last decade with the focus on their potential for further implementation and operational adoption by different organisations of the biopharmaceutical industry.

The 12 analysed frameworks/conceptual models and their key elements could be considered as a good background resources for co-development of industry-wide patient-centric standards and KPIs in close collaboration with patient experts, however nothing can be taken as originally designed and therefore implemented in a native format (lack of fidelity). Analysis of the modified IOCs showed that the PatientView, KINAPSE and PFMD frameworks have the highest implementation potential across the biopharmaceutical industry.

Albeit some frameworks and related key elements (PatientView and PFMD) are now being piloted in organisations, there is a common need for cross-functional and cross-industry discussions, piloting, validation and acceptance of the most adoptable key elements as standards and KPIs. All these steps must be done in close collaboration with patients and patient organisations to gain their continuous feedback, insights and advice. These steps and such a collaborative

approach should be integrated into corporate strategy and ways of working as workstreams on patient-centricity/patient affairs standards. These findings and interim milestones should be the subject for further research and publications.

References

1. Being Patient-Centric: An evidence-based self-evaluation toolkit for pharma… as recommended by patient groups. PatientView; November 2017.
2. CTTI Clinical Trial Transformation Initiative. CTTI recommendations: effective engagement with patient groups around clinical trials, October 2015. Access mode: https://www.ctti-clinicaltrials.org/files/pgctrecs.pdf.
3. Deane K, Delbecque L, Gorbenko O, et al. Co-creation of patient engagement quality guidance for medicines development: an international multi-stakeholder initiative. BMJ Innovation 2019; 0:1–13.
4. FasteCures Value Framework: Integrating the Patient Perspective into the Development of Value Frameworks, March 2016. Access mode: http://www.fastercures.org/reports/view/56.
5. Managing Performance in Patient Centricity. Making the link between value for patients and value for the pharmaceutical industry. A Kinapse white paper; 2015: https://info.kinapse.com/patient-centricity.html.
6. National Health Council (NHC) Framework Dialogue / Advancing Meaningful Patient Engagement in Research, Development, and Review of Drugs, September 22, 2015. Access mode: http://www.nationalhealthcouncil.org/sites/default/files/PatientEngagement-WhitePaper.pdf.
7. National Standards for Public Involvement in Research. Multi-stakeholder group: INVOLVE, National Institute for Health Research, 2017; Access mode: https://sites.google.com/nihr.ac.uk/pi-standards/home.
8. Patient Centricity Frameworks. A practitioner's guide; Eyeforpharma, December 2017.
9. PCORI Funded Projects: Sample Engagement Plans From Methods Portfolio, August 6, 2014. Access mode: http://www.pcori.org/sites/default/files/PCORI-Sample-Methods-Engagement-Plans.pdf.
10. PCORI Patient Engagement Rubric Engagement Rubric for Applicants, Feb 4, 2014 (updated June 6, 2016). Access mode: http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf.
11. People and Communities Board. Six principles for engaging people and communities: Definitions, evaluation and measurement. Published by the People and Communities Board, with support from National Voices, UK; June 2016; Access mode: https://www.nationalvoices.org.uk/sites/default/files/public/publications/six_principles_-_definitions_evaluation_and_measurement_-_web_high_res_0_1.pdf.
12. Perfetto et al. Framework: When is evidence sufficient for decision-making? A framework for understanding the pace of evidence adoption, in Journal of Comparative Effectiveness Research, July 2013, Vol. 2, No. 4, Pages 383-391. Access mode: http://www.futuremedicine.com/doi/pdfplus/10.2217/cer.13.39.
13. Proctor E, Silmere H, Raghavan R, et al. Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda. Adm Policy Ment Health (2011) 38:65–76.
14. Taylor J. Oral presentation at the Patient Summit Europe 2018, session "Discover the organisational blueprint for scaling patient centricity" / Being Patient-Centric: A National Voices Perspective; 16 October, London; https://s3.amazonaws.com/efpharma/patient2018/slides/D2-26+(b)+Jeremy.pdf.
15. University of Maryland M-CERSI Framework. Assessing meaningful patient engagement in drug development: a definition, framework, and rubric, March 2015. Access mode: http://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/centers/cersievents/pfdd/mcersi-pfdd-framework-rubric.pdf.

Дата надходження рукопису до редакції: 21.05.2020 р.

This work reflects the part 2 of our taskforce aimed to comprehensively analyse the selected 12 patient centricity frameworks/conceptual models and related key elements with the focus of their implementation potential and possible operational adoption by the biopharmaceutical industry.

Methods. The implementation potential of the key elements as unified standards, criteria or KPIs in the selected frameworks/conceptual models and their possible adoption across the biopharmaceutical industry were evaluated and discussed using modified Implementation Outcomes Criteria (IOCs), comprehensiveness, appropriateness, feasibility, fidelity, measurability, implementation resources, sustainability and scalability.

Results. Analysis against the modified IOCs showed that the PatientView, KINAPSE and PFMD frameworks have the highest implementation potential across the biopharmaceutical industry.

Conclusions. None can be taken as prototype as originally developed. There is a common need for cross-functional and cross-industry discussions, further piloting, validation and acceptance of the more adoptable key elements as standards and KPIs. These must be co-developed in close collaboration with patient experts, then integrated into corporate strategy and ways of working as workstreams on patient centricity/patient affairs standards.

Ця робота виконана в якості другої частини завдання щодо всебічного аналізу 12 вибраних рамкових платформ і концептуальних моделей пацієнт-орієнтованості, а також пов'язаних з ними ключових елементів, з фокусом на потенціал їхнього впровадження та застосування на операційному рівні організаціями біофармацевтичної галузі.

Методи. Було оцінено та обговорено потенціал для впровадження та більш широкого прийняття вибраних елементів у якості уніфікованих стандартів, критеріїв або ключових індикаторів виконання завдань на галузевому рівні, – із використанням модифікованих критеріїв оцінки результатів впровадження (IOCs), а саме критеріїв всебічності, прийнятності, здійсненості, точності відтворення базового прототипу, вимірюваності, потреб у ресурсах, сталості у часі і відтворюваності в різних умовах.

Результати. Аналіз із використанням модифікованих критеріїв оцінки результатів впровадження (IOCs) показав найвищий потенціал щодо впровадження біофармацевтичною галуззю таких платформ, як PatientView, KINAPSE та PFMD.

Висновки. Жодна з аналізованих рамкових платформ/концептуальних моделей не може бути використана в якості прототипу без змін. Існує нагальна потреба щодо подальших міжфункціональних та міжгалузевих дискусій, набуття практичного досвіду, валідації і загального прийняття найбільш узгоджених основних елементів в якості стандартів і ключових індикаторів виконання завдань. Вони мають бути обґрунтовані і узгоджені в тісній співпраці з експертами пацієнтської спільноти, після чого інтегровані у корпоративні стратегії як стандарти роботи з пацієнтами.

Данная работа была выполнена в качестве второй части задания по всестороннему анализу 12 выбранных рамочных платформ и концептуальных моделей пациент-ориентированности, а также связанных с ними ключевых элементов, с фокусом на потенциал их внедрения та применения на операционном уровне организациями биофармацевтической отрасли.

Методы. Была проведена оценка и обсужден потенциал для внедрения и более широкого принятия выбранных элементов в качестве ключевых стандартов, критериев или ключевых индикаторов исполнения заданий на отраслевом уровне, – с использованием модифицированных критериев оценки результатов внедрения (IOCs), а именно критериев комплексности, допустимости, выполнимости, точности воспроизведения базового прототипа, измеримости, потребности в ресурсах, постоянства во времени и вопроизводимости в разных условиях.

Результаты. Анализ с использованием модифицированных критериев оценки результатов внедрения (IOCs) показал наивысший потенциал в отношении внедрения биофармацевтической отраслью таких платформ, как PatientView, KINAPSE и PFMD.

Выводы. Ни одна из проанализированных рамочных платформ/концептуальных моделей не может быть использована в качестве прототипа без изменений. Существует общая необходимость в отношении дальнейших межфункциональных и межотраслевых дискуссий, приобретении практического опыта, валидации и общего принятия наиболее согласованных элементов в качестве стандартов и ключевых индикаторов выполнения заданий. Они должны быть обоснованы и согласованы в тесном сотрудничестве с представителями пациентского сообщества, после чего интегрированы в корпоративные стратегии как стандарты работы с пациентами.

Конфлікт інтересів: відсутній.
Conflicts of interest: authors have no conflicts of interest to declare.

Відомості про авторів

Gorbenko Oleksandr – MD, PhD, Global Director, Patient Affairs, ViiV Healthcare, TW8 9GS, 980 Great West Road, Brentford, Middlesex, United Kingdom.
algostand@gmail.com.

Williams Merlin – MSc, Senior Consultant, Executive Insight Healthcare Consultants AG, Baar, Switzerland.
m.williams@executiveinsight.ch.