Considerations for Developing and Implementing Patient-Centered Initiatives



Metrics in Patient-Centered Drug Development Conference

Patient centricity is rapidly becoming the central theme of next-generation health care product development around the globe.

Patient centricity can be simply defined as integrated measures for listening to and partnering with patients. Patient centricity places patient well-being at the core of all initiatives. Combined with the emergence of the partnership of patients in health care and the wider health ecosystem, is a result of the sense of autonomy gained by people and patients over the previous six decades.

Along the journey from a time of paternalistic health care to present day, in which the patient community is asserting its role as a partner in its own care, there is growing awareness that the patient should be meaningfully involved in the drug development process. The Future of Patient Engagement Measuring What Matters

> Capturing the Value of Patient Engagement: Summary of Results of the 2016 Study of Patient-Centric Initiatives in Drug Development

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Considerations Guide to Implementing Patient-Centric Initiatives in Health Care Product Development

VIEW GUIDE

As awareness and theory around patient-centric medical product development have matured, discussion about measuring the value of patient engagement, including quantification of return on engagement (ROE), has increased.

A growing number of engagement approaches and methods are available for adoption and use, but there is little documentation of ways to measure their contribution to the desired outcomes of a therapeutic development program.

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To optimize the human and financial resources that are dedicated to patient engagement efforts, by both industry and patient stakeholders, it is important to be able to quantify the impact of the selected efforts.

Though there is currently little guiding regulatory policy around acceptable approaches to patient-centered medical product development, the area is progressing with growing consensus around its importance.



Patient Partners: Power That Rests in Us All

Commentary by Debra Lappin, Head of the Health Biosciences Practice for FaegreBD Consulting



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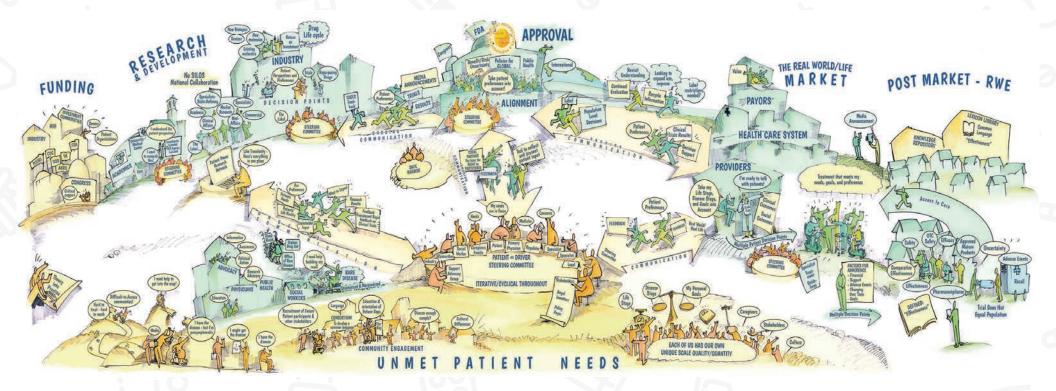
Patient Value Should Drive Market Value

An interview with Co-Founder. President, and Chief Privacy Officer at PatientsLikeMe, Ben Heywood





Visual Model of Patient Engagement



COLOR KEY

Green: denotes aspects of patient engagement in place, with efforts begun

Yellow: denotes aspects that are not now in practice but should be implemented in the medical product life cycle for effective and meaningful patient engagement

Drivers Behind the Patient Centricity Push

Patients and public work have moved industry to awareness and readiness to meaningfully engage patients in the medical product life cycle. A growing number of <u>engagement approaches</u> and methods are available for adoption and use, but there is little documentation of ways to measure their contribution to the desired outcomes of a therapeutic development program.



Industry stakeholders are moving from awareness/acceptance of the concepts of patient-centered product development to action and implementation



Stakeholders want and need to incorporate the patient voice regardless of the current absence of regulatory guidelines



Different perspectives within the same organization: for industry, this creates a need to demonstrate the effective use of resources for patient-centered initiatives/actions

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The commitments of PDUFA VI include a series of patient engagement guidances intended to ensure that the patient voice is included throughout the medicines life cycle

MDUFA IV commitments include implementation of CDRH's strategic plan to promote a culture of meaningful patient engagement within CDRH and to increase the use of patient input as evidence in regulatory decision-making Get up-to-speed on the current policy landscape for patient engagement in the medical product development life cycle and its impact on the needs of industry stakeholders in measuring engagement outcomes at DIA's <u>Metrics</u> in Patient-Centered Drug Development Conference

The medical products industry is at a critical juncture, with an opportunity to define medical product development operational activities and measures that will support the growth of patient centricity.

Return on investment (ROI) is a key metric for business performance, and well-functioning organizations typically bring their stakeholders high ROI. The "return on" concept can also be applied in measuring how well organizations engage with their customers. The challenge is identifying the metrics that show the value of return on meaningful engagement.

Patient engagement metrics can clarify and elevate the value proposition of patient-centric initiatives (PCIs) and can help an organization's leadership steer resources and focus toward true patient centricity. Industry is still reaching to find the right mix of metrics to measure true ROE.



Trial Return on Engagement: Quantifying Benefits Of Patient-Centric Initiatives



DIA's <u>Metrics in Patient-Centered Drug Development Conference</u> will explore a recently developed ROE "toolkit" that maps PCIs to examples of metrics that are in use to quantify ROE which illustrates:

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Trial performance improves: faster planning, approval, and enrollment; fewer protocol amendments

Metrics in Patient-Centered Drug Development Conference

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Study volunteer feedback is more positive and patient activation measures (PAM) scores are higher



Internal and external reach improves, particularly with use of technology



Long-term drug development portfolio improves as companies can lower development costs through relatively inexpensive PCIs



Submit an abstract by September 23, 2017 for review.



DIA's <u>Metrics in Patient-Centered Drug Development Conference</u> will examine the core principles of measuring the ROE of patient engagement and demonstrate how current and emerging approaches are being applied by industry colleagues to measure engagement impact on outcomes of importance to patient, industry, regulatory, and payer stakeholders.

Quantifying the Impact of Patient Engagement

Why? How? What research has informed the development of impact metrics to document process and outcome improvements? What are methods of developing consensus ROE metrics?

Defining Return on Engagement - Measuring What Matters

How can stakeholder-relevant metrics be designed and demonstrate accountability in patient-centric initiatives?

The Emerging Role of the Patient in an Evolving Health Ecosystem

How will coming changes in the health care ecosystem intensify the importance of demonstrating patient centricity in drug development?

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Case Examples of the Impact of Engagement

What are some real-world examples of organizations that have measured the impact of their patient-centered initiatives? How did they do it, and how will the results inform their future work?



Cultural Change - A Key to Advancing Patient Centricity in Drug Development

How have leaders and innovators in patient-centered medical product development changed the culture of their organizations to support patient-centeredness?



Why Attend?

DIA's Metrics in Patient-Centered Drug Development Conference Will:

- Provide open discussion among multiple stakeholders, including regulators, about the current policy environment for patient-centric medical product development and approval, as well as directions to be taken in the coming months to clarify policy and guidelines
- Examine the core principles of measuring the ROE of patient engagement
- Demonstrate how current and emerging approaches are being applied by industry to measure engagement impact on outcomes of importance to patient, regulatory, and payer stakeholders

- Take a deep dive into new resources for assessing and documenting the impact of patient engagement
- Ignite discussions with companies that have effectively addressed key barriers to becoming patient-centric organizations
- Provide a valuable resource when addressing challenges and resolving problems in the design and implementation of patient-centric initiatives and ROE measures

Patient-centeredness in the medical product life cycle is a global topic, with Europe and the US having the longest experience with addressing patient engagement issues.

Attend DIA's <u>Metrics in Patient-Centered Drug Development Conference</u> to apply these four focus factors to your own medical product development (and life cycle management) programs:

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The "how" of measuring the impact of patientcentered efforts on stakeholder objectives

Metrics in Patient-Centered Drug Development Conference

ROE metrics and other resources developed and in use by industry peers

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Approaches to developing organizational cultures that support patient-centric practices in the medical product life cycle; how patient engagement metrics can help change the culture

Metrics for patient organizations to assess the impact of the resources they dedicate to engagement relationships and sharing of their resources



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Key sessions spotlighting the "how" of quantifying the impact of patient engagement through metrics

- Quantifying the Impact of Patient Engagement
- Quantifying the Impact of Engagement: View
 Through the Patient Lens
- Defining Return: Measuring What Matters
- Resources for Patient Engagement Metrics

More Must-Attend Sessions

- Cultural Change A Key to Advancing Patient Centricity in Drug Development
- Case Examples of the Impact of Engagement
- <u>The Emerging Role of the Patient in an</u> <u>Evolving Health Ecosystem</u>

Learn more about DIA and join the DIA Overview session, October 19, at 8:00AM.



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Continue the Conversation in in DIA's Patient Engagement Community

Join the Community to help increase awareness and contribute to the shaping of global legislation for medical devices, in vitro diagnostics, and combination products. Our neutral forum also allows industry, research organizations, academia, and regulators to 'cross the aisle' in dialog on these topics.

Other reasons to join a DIA Community:



Network with colleagues across the globe



Share best practices



Contribute your voice to the conversation

Community Spotlight: Patient Engagement Community: Co-Developing Medicines with Patients as Partners

READ MORE

DIA's Communities are open to all DIA members

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5 Ways to help you keep up to date with the changing health care landscape



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