Capturing the Value of Patient Engagement:

Summary of Results of the 2016 Study of Patient-Centric Initiatives in Drug Development

January 31, 2017
Patient Engagement in the Lifecycle of Medical Products

**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.
Today’s Agenda

Key Insights
Research Findings
Disseminating Results
Next Stage of Research
Your Questions & Comments
In Collaboration With

Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY
Timeline for Study

January 2016
Initiate research project

June 2016
Report interim results at DIA Annual Meeting

September 2016
Finalize data and findings

October 31, 2016
Share results

January 2017
Share findings
Launch follow-on research
Objectives of the Research

- Quantify the impact of patient-centric initiatives to derive ROE
  - Based on retrospective data from actual experience
- Assess adoption of various patient-centric
- Characterize management and organizational models
- Identify guidance and frameworks to inform implementation
Key Insights

- 121 actual case examples containing several hundred metrics identified and analyzed
  - Low cost engagement initiatives generate the highest ROE; high tech initiatives show lower ROE
  - Metrics are not uniformly defined, making it hard to compare and generalize at this time

- ROE metrics show that:
  - Trial performance improves (faster planning, approval, enrollment; fewer protocol amendments)
  - More positive study volunteer feedback; Patient Activation Measures (PAM) scores are higher
  - Long-term savings across drug development portfolio
Key Insights (continued)

- Most widely adopted engagement initiatives include patient advisory boards, site advisory boards, clinical trial results summaries
  - A high percentage of companies are piloting end-of-trial surveys and the use of wearable devices
  - Poor internal buy-in and inadequate authority to implement are primary adoption barriers

- Wide variation observed in organizational models supporting the implementation of patient engagement initiatives

- Regulatory agencies, disease organizations and private sector companies have all embraced patient centricity, and they are all developing frameworks and resources
Research Methodology

- Conduct industry survey
  - to map landscape of patient centric initiatives
  - to examine organizational roles/structures and management practices

- Interview company representatives on management strategy and practices

- Collect case studies of patient-centric approaches

- Conduct metrics toolkit feasibility survey

- Identify available guidance and frameworks
Components of the Research

- ROE Metrics
- Patient-Centric Initiatives
- Management Practices & Models

Guidances, Frameworks, & Considerations
Return on Engagement Toolkit

- **PCI Cost** (e.g. total cost; cost per trial; percentage of overall trial cost; cost per evaluable patient; cost per submission program)
- Overall **development timelines** (includes time to go/no-go decisions; comparisons to traditional trial timelines)
- Overall **program success rate** relative to portfolio benchmark
- **Regulatory activity** with study volunteers

**Long-Term Drug Development Portfolio**

- **Total number of PCIs** implemented
- **Total number of trials** using PCI (overall and percent of total trials; planned and completed)
- **Total number of study volunteers / PAGs involved in PCI** (e.g. # ambassadors; # alumni)

**Internal and External Reach**

- **Study volunteer feedback and satisfaction** to FDA/site/sponsor on study drug/clinical trial (e.g. interviews; surveys; QOL / PRO; % positive responses over total; perspective on important procedures; receptivity to protocol; types and number of missed assessments)
- **Total number of changes** (e.g. protocol; communication and program positioning) from study volunteer feedback and how changes impacted program/study design

**Study Volunteer Feedback**

- **Study volunteer metrics** (e.g. screening, recruitment, and retention rates)
- **Trial cycle times and length**
- **Number of protocol amendments** and changes from amendment
- Whether clinical trial went into **rescue** when using PCI
- Changes in **protocol complexity**; # endpoints relevant to patient groups

**Trial Performance**

- Stratification variables:
  - PCI Type
  - Disease indication
  - Study phase
  - Maturity of PAGs


Data and analysis provided by Tufts CSDD
Patient-Centric Initiatives† (PCI) by Category

**Innovative Partnerships**
- Patient group support and involvement
- Patient advisory boards and focus groups*
- Professional panels
- Community conversations
- Medicine co-development partnerships with patient groups
- Patient group landscape analysis tool (disease area specific)

**Protocol Design**
- Adaptive trial designs and adaptive licensing
- Open design and crowdsourcing
- Patient involvement in study feasibility and design
- Protocol feasibility review committees
- Real world, practice-based clinical trials

**Technology Advancements**
- Apps for clinical data collection/analytics
- Digital medicine**
- Direct-to-patient clinical trials/telemedicine
- E-Consent
- Gaming
- Social Media/Online Engagement
- Human factor testing/simulation
- Centralized/integrated HER & clinical records
- Patient wearable device

**Study Volunteer Ease**
- Home nursing networks and logistics assistance
- Patient counseling and education
- Patient trial community during trials and after trials
- Lay summary clinical trial results
- End of study surveys

† Only those PCIs reported in the case studies.
*Includes groups such as NIHR (National Institute for Health Research).
** Medicine that can be tracked using technology.
## Types of Metrics Collected

<table>
<thead>
<tr>
<th>Category</th>
<th>Quantitative Metrics</th>
<th>Qualitative Metrics (Benefits)</th>
<th>Qualitative Metrics (Challenges)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advocacy Group Support And Involvement</td>
<td>42</td>
<td>124</td>
<td>67</td>
</tr>
<tr>
<td>Direct-To-Patient Clinical Trials / Telem medicine</td>
<td>55</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>Apps For Clinical Data Collection</td>
<td>50</td>
<td>41</td>
<td>24</td>
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<tr>
<td>Advisory Panels</td>
<td>40</td>
<td>7</td>
<td>52</td>
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<tr>
<td>Social Media/Online Engagement</td>
<td>33</td>
<td>60</td>
<td>39</td>
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<tr>
<td>Patient Counseling And Education</td>
<td>10</td>
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</tr>
<tr>
<td>Crowdsourcing</td>
<td>11</td>
<td>6</td>
<td>6</td>
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<tr>
<td>Adaptive Trial Designs</td>
<td>9</td>
<td>35</td>
<td>15</td>
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<tr>
<td>Home Nursing Networks</td>
<td>6</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>E-Consent</td>
<td>2</td>
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</tr>
<tr>
<td>Gaming</td>
<td>1</td>
<td></td>
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</tr>
<tr>
<td>Digital Medicine</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Number of Metrics Collected**
### Top ROE Metrics Collected

<table>
<thead>
<tr>
<th>Metric</th>
<th>% of Respondents that Rated Metric Very Valuable to Determining ROE</th>
<th>% of Respondents that Rated Metric Extremely Easy to Collect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Development Cycle Time</td>
<td>100%</td>
<td>27%</td>
</tr>
<tr>
<td>The Number of Patient Volunteers Reached during Time Frame</td>
<td>91%</td>
<td>0%</td>
</tr>
<tr>
<td>Overall Patient Satisfaction in a Given Study</td>
<td>91%</td>
<td>20%</td>
</tr>
<tr>
<td>Cost of Patient Centric Approaches</td>
<td>83%</td>
<td>17%</td>
</tr>
<tr>
<td>Patient Centric Initiative Used in Protocol</td>
<td>82%</td>
<td>30%</td>
</tr>
<tr>
<td>Number of Drop Outs (not due to SAE or AE)</td>
<td>82%</td>
<td>67%</td>
</tr>
<tr>
<td>Number of Changes to the Protocol Due to the Amendment</td>
<td>80%</td>
<td>44%</td>
</tr>
<tr>
<td>Study Conduct Duration (First Patient In to Last Patient Out)</td>
<td>80%</td>
<td>78%</td>
</tr>
</tbody>
</table>

% of Respondents that Rated Metric Very Valuable to Determining ROE

% of Respondents that Rated Metric Extremely Easy to Collect
Summary Findings: Current Cost and Impact Overall

<table>
<thead>
<tr>
<th>Patient-Centric Initiative</th>
<th>Cost to Conduct</th>
<th>Ease of Conducting</th>
<th>Reported Impact*</th>
<th># Collected Quantitative Metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advocacy Group Support and Involvement</td>
<td>$</td>
<td>$</td>
<td>✔ ✔ ✔ ✔</td>
<td>42</td>
</tr>
<tr>
<td>Patient Advisory Panels and Focus Groups</td>
<td>$</td>
<td>$</td>
<td>✔ ✔ ✔ ✔</td>
<td>40</td>
</tr>
<tr>
<td>Social Media/Online Engagement</td>
<td>$</td>
<td>$</td>
<td>✔ ✔ ✔ ✔</td>
<td>33</td>
</tr>
<tr>
<td>Patient Counseling and Education</td>
<td>$</td>
<td>$</td>
<td>✔ ✔ ✔ ✔</td>
<td>10</td>
</tr>
<tr>
<td>Adaptive Trial Designs and Adaptive Licensing</td>
<td>$ $</td>
<td>$ $</td>
<td>✔ ✔ ✔ ✔</td>
<td>9</td>
</tr>
<tr>
<td>Open Design and Crowdsourcing</td>
<td>$</td>
<td>$</td>
<td>✔ ✔ ✔ ✔</td>
<td>11</td>
</tr>
<tr>
<td>Direct-To-Patient Clinical Trials / Telemedicine</td>
<td>$ $</td>
<td>$ $</td>
<td>✔ ✔ ✔ ✔</td>
<td>55</td>
</tr>
<tr>
<td>Home Nursing Networks and Logistics Assistance</td>
<td>$ $</td>
<td>$ $</td>
<td>✔ ✔ ✔ ✔</td>
<td>6</td>
</tr>
<tr>
<td>Apps For Clinical Data Collection</td>
<td>$ $ $</td>
<td>$ $ $</td>
<td>✔ ✔ ✔ ✔</td>
<td>50</td>
</tr>
<tr>
<td>E-Consent</td>
<td>$ $</td>
<td>$ $</td>
<td>✔ ✔ ✔ ✔</td>
<td>0</td>
</tr>
<tr>
<td>Digital Medicine</td>
<td>$ $ $</td>
<td>$ $ $</td>
<td>✔ ✔ ✔ ✔</td>
<td>1</td>
</tr>
<tr>
<td>Gaming</td>
<td>$ $ $</td>
<td>$ $ $</td>
<td>✔ ✔ ✔ ✔</td>
<td>1</td>
</tr>
</tbody>
</table>

Rubric out of four dollar signs, weight lifters, or check marks. Ratings relative to each other and based on case study data.

* Impact assesses changes in quality; speed; and impact on patient.

Data and analysis provided by Tufts CSDD
Each PCI Category Maps to ROE Metrics

Innovative Partnerships
Protocol Design
Technology Advancements
Study Volunteer Ease

- Long-Term Drug Development Portfolio
- Internal and External Reach
- Study Volunteer Feedback
- Trial Performance
Case Examples of Impact from: Innovative Partnerships

- **Cost** of working with PAGs / patient advisory boards
  - minimal
  - up to $100K in donations
  - ~$100-$250 / patient (in-depth interviews)
  - $1K-$40K / focus group
- “[PAGs] saved millions of dollars” --- CRO
- “Data [gathered] can be used across all clinical trials” --- Sponsor

- On average 1-2 PAGs per clinical trial consulted
  - Focus groups / in-depth interviews consist of ~8-10 study volunteers per clinical trial
  - Survey outreach range from ~200 to ~400 study volunteers

- Mean number of changes from PAGs: 12.4 changes (range: 3-17)
  - Patient advisory boards have reported on average:
    - 1.3 changes to schedule of visits
    - 1.5 changes to number of procedures
    - 3.8 changes to informed consent form
    - 7 changes to study positioning and communication material

- Initial planning time: 3 months (in future should take 3 weeks)
  - IRB approval: 1 month
  - “Faster study enrollment” --- Sponsor
  - Faster FDA approval of protocol
  - Randomization rates ranging from 8% to 100%

Long-Term Drug Development Portfolio (N=2 metrics)

Internal and External Reach (N=3 metrics)

Study Volunteer Feedback (N=55 metrics)

Trial Performance (N=22 metrics)

53 Case Studies Found.

Data and analysis provided by Tufts CSDD
Examples of Impact from Protocol Design Input

- **Open Design*/Crowd-sourcing* reported to reduce clinical trials costs by 60%
- **Stopping early for efficacy**
  - Saved the company $4 million on phase III trial by stopping trial 1 year early to bring drug to market early
  - Tripled company stock price
- **Sample size re-estimation (SSR)** produced on average 15% savings of overall trial costs (20% smaller sample was required)

**Long-Term Drug Development Portfolio** (N=4 metrics)

**Internal and External Reach** (N=5 metrics)

**Study Volunteer Feedback** (N=4 metrics)

**Trial Performance** (N=6 metrics)

10 Case Studies Found.
Examples of Impact from Tech Advancements*

- **Cost varies by sophistication of app and wearable device**
  - ~$30K for bare-bones **app development**
  - $100- $250 per wearable device
- **“Reduced costs by 50%”** --- PI of study (no wearable used; using Apple Research Kit)
- **Telemedicine** studies report savings from 12% of clinical trial costs 163% increase (median 50% savings)

**Long-Term Drug Development Portfolio (N=7 metrics)**
- **Cost varies by sophistication of app and wearable device**
- **Apple Research Kit:**
  - 11,000 individuals signed up for CVD study on first day
  - Number of participants range from 1,600 to 44,841
  - 31 countries represented
  - # study volunteers using telemedicine: 1,200 – 10,600 screened; 150 – 1,200 enrolled

**Internal and External Reach (N=9 metrics)**
- **Telemedicine study volunteer feedback**
  - Positive patient feedback varies on type of wearable device
  - **Gaming PROs higher** for gaming group than non-gaming group

**Study Volunteer Feedback (N=23 metrics)**
- **Telemedicine study volunteer feedback**
  - Positive patient feedback varies on type of wearable device
  - **Gaming PROs higher** for gaming group than non-gaming group

**Trial Performance (N=91 metrics)**
- IRB Approval: **2.5 years** to obtain**
  - **Retention rates:**
    - Watch device: average 81%
    - Other device: average 63%
    - Telemedicine: 76%-93%
    - Gaming: ↑ by 16%
  - E-Consent: modest improvements
  - E-Consent reports minimal improvements in comprehension
  - **Telemedicine studies** report enrollment rates from 0% to 50%; timeline reductions

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48 Case Studies Found.

* Excludes Social Media and Online Engagement
** Publishing platform containing informed consent, study protocol and supporting documents
Examples of Impact from **Study Volunteer Ease**

- **Logistics assistance** costs 1% of clinical trial budget

- Study using **Logistics assistance** incorporated patients from other countries into **one site instead of opening multiple sites**

- **Feedback from Patient Counseling and Education report:**
  - Increase in PAM score
  - 70% difference in satisfaction rates (counseling group was higher)

- Survey of 63 companies using **Patient Counseling and Education** report 85% enrollment rate:
  - “Much of the success of the multifaceted and adaptive patient consent and enrollment approach is due to the role of nursing in providing education…”
  - Home nursing:
    - 300%↑ in patient enrollment
    - 64%↑ in patient retention
    - Logistics assistance: 95% retention rate

7 Case Studies Found.
Most widely adopted (implemented and piloted) initiatives are:
- Patient advisory boards (17/22 companies)
- Professional panels (16/22)
- Lay-language clinical trial results summaries (13/22)
- Assessment of patient organization landscape (10/22)
- Use of home nursing networks (9/22)

Top planned initiatives are:
- eConsent (11/22)
- Adaptive trial designs and adaptive licensing (10/22)
- Establishing patient communities (during and after clinical trials) (10/22)

Overall, there are more organizational patient-centric activities in the planning stages than those being implemented or piloted.
The most implemented initiatives were patient organization landscape analysis tools, patient advisory boards, and professional panels.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Number of Companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient organization landscape analysis tools</td>
<td>10</td>
</tr>
<tr>
<td>(disease area-specific)</td>
<td></td>
</tr>
<tr>
<td>Patient advisory boards</td>
<td>10</td>
</tr>
<tr>
<td>Professional panels</td>
<td>10</td>
</tr>
<tr>
<td>Use of home nursing networks</td>
<td>9</td>
</tr>
<tr>
<td>Community conversations</td>
<td>7</td>
</tr>
<tr>
<td>Lay-summary clinical trial results</td>
<td>7</td>
</tr>
<tr>
<td>Innovative patient data analytics/collection</td>
<td>7</td>
</tr>
</tbody>
</table>

Base: 22 Companies
Patient-Centric Initiatives - Piloted

The top piloted initiative was an **end of study survey**.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Number of Companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>End of study survey</td>
<td>9</td>
</tr>
<tr>
<td>Patient wearable devices</td>
<td>8</td>
</tr>
<tr>
<td>E-consent</td>
<td>7</td>
</tr>
<tr>
<td>Patient involvement in study feasibility and study design</td>
<td>7</td>
</tr>
<tr>
<td>Professional panels</td>
<td>6</td>
</tr>
<tr>
<td>Protocol feasibility review committees</td>
<td>6</td>
</tr>
<tr>
<td>Lay-summary clinical trial results and/or risk management report</td>
<td>6</td>
</tr>
</tbody>
</table>

*Base: 22 Companies*
The top planned initiative was e-consent.
The top initiatives companies are not considering are the medicine co-development partnerships with patient associations and open design and crowdsourcing.

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Number of Companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine co-development partnerships with patient associations</td>
<td>16</td>
</tr>
<tr>
<td>Open design and crowdsourcing</td>
<td>16</td>
</tr>
<tr>
<td>Telemedicine</td>
<td>12</td>
</tr>
<tr>
<td>Direct-to-patient clinical trials</td>
<td>9</td>
</tr>
<tr>
<td>Real world, practice-based clinical trials</td>
<td>8</td>
</tr>
<tr>
<td>Human factor testing/simulation</td>
<td>8</td>
</tr>
</tbody>
</table>

Base: 22 Companies
Key Insights

- The primary barriers to adoption are the lack of:
  - internal company buy-in (6 of 22 companies)
  - authority to implement them (5 of 22 companies)

- Others barriers include (perceived) lack of sponsor readiness, risk tolerance, staff, time, and budget
  - 13 out of 20 companies responded there is an organizational budget assigned for patient engagement activities.
  - 6 out of 20 companies responded they did not have a budget for these activities.
  - 1 company did not respond.
Wide variation in approaches observed

Most prevalent model: Centralized, dedicated function

Responsibilities include:
- Facilitate cultural change within organization
- Build policies, guidelines, processes and tools
- Share effective practices across the company
- Advance more systematic patient centricity company-wide
- Facilitate and coordinate implementation
- Manage internal alignment of patient engagement and advocacy outreach efforts

Note – function does not implement PCIs and does not have funding or approval authority for PCIs

Comments

Most companies with a dedicated patient engagement role say it has had an impact on the business by translating to key operational changes

However, most companies do not have or use metrics to measure the impact of the role
Decentralized Patient Engagement functions:

- Leadership teams comprised of representatives from multiple functions
- Teams are not centralized but have visibility to and strong support from senior leadership
- Scan the company landscape, pilot patient engagement approaches, scale up successful approaches, establish support for operationalization, and disseminate appropriate practices company-wide
- Patient engagement efforts are initiated in the functional units throughout the company

Patient Engagement as “Strategic Core”:

- Expectation for patient engagement to take place is core to company strategy
- No single group is responsible for overseeing or supporting PE efforts
- Leadership ensures that PE is part of all strategic planning via policies, processes, and oversight
- PE activities take place within multiple functions throughout the company
## Organizational Structure & Functions for Patient Engagement

<table>
<thead>
<tr>
<th>Companies with Dedicated PE Role</th>
<th>Large (n = 4)</th>
<th>Mid-sized (n = 3)</th>
<th>Small (n = 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Leadership Structures – PE Role Via:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-Level Patient Office</td>
<td>2</td>
<td>1</td>
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<tr>
<td>Collaborative Leadership Teams</td>
<td>2</td>
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<td>---</td>
</tr>
<tr>
<td>Pt Advocacy Team: Internal &amp; External Roles</td>
<td>1</td>
<td></td>
<td>---</td>
</tr>
<tr>
<td>Small Internal Coordinating Team</td>
<td>1</td>
<td></td>
<td>---</td>
</tr>
<tr>
<td>Small Central Team to Coordinate &amp; Oversee</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple Staff Members on Team</td>
<td>4</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Bridge R&amp;D and Commercial</td>
<td>4</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Global Focus</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Dedicated PE Budget</td>
<td>4</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Adequate Budget for PE Objectives</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>
## Organizational Structure & Functions for Patient Engagement

<table>
<thead>
<tr>
<th>Companies with NO Dedicated PE Role</th>
<th>Large Companies (n = 3)</th>
<th>Mid-sized Companies (n = 3)</th>
<th>Small Companies (n=0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PE Taking Place in Multiple Functional Areas:</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Clinical Development /Operations</td>
<td>3</td>
<td>2</td>
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<tr>
<td>Patient Advocacy</td>
<td>3</td>
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<tr>
<td>Medical Affairs</td>
<td>3</td>
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<tr>
<td>Government/External Relations</td>
<td>2</td>
<td>0</td>
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</tr>
<tr>
<td>Corporate Affairs</td>
<td>2</td>
<td>1</td>
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</tr>
<tr>
<td>Communication Among Functions</td>
<td>3</td>
<td>3</td>
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<tr>
<td>Communications Bridge R&amp;D &amp; Commercial</td>
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<tr>
<td>Global Focus</td>
<td>1</td>
<td>0</td>
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<td>Dedicated PE Budget</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Adequate Budget for PE Objectives</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
Regulators are embracing patient-centricity and plan to develop more guidance for industry in the future (e.g., PDUFA VI), but little is available now.

Existing regulatory guidance is specific to what can be measured, e.g., patient-reported outcomes (PROs).

No single guidance document or resource covers all aspects of patient-centric drug development, but a compilation of all existing tools comes close.

Multiple organizations are working on developing tools, generally from one of two perspectives: data-driven and people-driven.

Toolkits and other resources more often deal with the less scientific aspect of patient-centric drug development (e.g., communications, training, relationship building, trial participant interactions).
Evolving Data Collection for Guidances & Frameworks

**Regulators (FDA/EMA):**
- Guidance documents (*few but with more coming w/ PDUFA VI*)
- Patient-centricity an evolving focus

**Other Government Organizations:**
- Focus on wider public health concerns
- ‘Community’ vs. ‘patient’ engagement
- Grant funding tied to patient-centric processes

**Research Collaborations:**
- No common focus or theme
- Mixture of literature reviews and high-level ‘how to’ recommendations

**NGOs/Patient Groups/Public-Private Partnerships:**
- Patient-centric practices and ‘how to’ resources
- Mixed degree of scientific data & rigor
Considerations Guide & Practical “How to”

Developed a ‘Considerations Guide’

- Designed to facilitate the development of a customized patient-centric initiative
- Collects and directs users to various resources currently available
Access these Patient Engagement Resources at www.diaglobal.org:

Download:
- Visual model of Patient Engagement
- Research Summary
- PCI Considerations Guide

Join the conversation on the DIA Patient Engagement Community.
Patient Engagement on the Agenda: Global Annual Meeting

Full Track of 14 Patient Engagement Sessions, including:

Monday June 19:
8:00 AM Capturing the Value of Patient Engagement: State of the Art
10:45 AM Patient Engagement: 4 W’s and an H

Tuesday June 20:
10:30 AM Walking the Walk in Patient Focused Medicines Development: What Have We Learned?
2:00 PM Defining the Science of Patient Input to Enhance Drug Development & Approval: Regulatory Perspectives
4:00 PM Defining the Science of Patient Input to Enhance Drug Development & Approval: The Tools

Visit www.diaglobal.org/flagship/dia-2017 for more information

Fall 2017 Workshop: Patient Engagement Metrics – How Can We Capture Value?
Visit www.diaglobal.org for information, details coming this Spring!
Roundtable with IMI:

The discussion will aim to demonstrate the value of patient involvement in medicines R&D, and will address the following questions and issues:

- What does patient centricity mean to different stakeholders?
- Why do we need patients to be engaged at an early stage of medicines development?
- What are the lessons learned from existing cases?
- What are the challenges in early patient involvement?
- How should patients be engaged for the impact to be real and meaningful?

Invitation to Join the Next Phase of Research

DIA and Tufts CSDD are planning the next phase of research:

- **Objectives**: Development of best practice recommendations and standardized metrics definition and usage; application and refinement of tools and resources; ongoing compilation of ROE impact case studies

- To be conducted Q2 2017 through Q1 2018

- Working group of sponsor and CRO companies will meet to review and discuss patient engagement experiences, challenges and insights

- Facilitated roundtable meetings with guest speakers from public and private sectors
We’ve made a significant contribution to this important topic and look forward to continuing this work with your support.

For expressions of interest and recommendations for follow-on research, please contact: Elizabeth.Lincoln@DIAGlobal.org

Want more on Patient Engagement news, initiatives, and follow-on work? Visit "How We Think" for more.