The Pharma Industry in the Learning Health System

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All stakeholders win in a connected health ecosystem

In the Learning Health System, fragmented parts of the health ecosystem are connected so that data, information, and evidence can **flow** more efficiently.

This flow facilitates more rapid learning and enables us to progress on the goals we all share:

1. Improved quality of care
2. Reduced errors
3. Reduced costs
4. Faster impact of innovation (reduced time lag for knowledge translation)

What can pharma contribute to the Learning Health System?

1. Faster, patient-centered drug development
2. Clinical trial data
3. Real world evidence
4. Drug information
5. Deep disease state knowledge (e.g., non-branded health ed materials)
6. Continuing progress toward personalized medicine
7. Deep analytics expertise
8. Non-medical expertise such as knowledge management, other in the pre-competitive space (e.g., investigator databases)
9. Staffing
10. Funding

Opportunities for pharma in the Learning Health System

1. **Faster, patient-centered drug development**:
   - Design trials and real world studies to measure what patients value
   - Make clinical trials more convenient for patients
   - Increase enrollment in clinical trials
   - Make clinical trials a care option

2. **Improved, appropriate access to data for**…
   - Improved safety surveillance
   - Generating real world evidence
   - Enabling personalized medicine
   - Improved hypothesis generation

3. **Appropriate and more efficient evidence dissemination**:
   - Disseminate our clinical trial and real world evidence more efficiently as needed at the point of care
   - Reducing the appalling 17 year gap
   - Increasing the impact of innovation

How can pharma help create the Learning Health System?

1. Advance the LHS vision
2. Help plan and build
3. Spread the word – inside and out
4. Learn and prepare

How can pharma help create the Learning Health System? continued

1. Advance the LHS vision:

- Raise awareness of the LHS in your organization
- Secure executive advocacy
- Coordinate your organization formally endorsing the LHS Core Values
- Make a financial contribution to the Learning Health Community
- Host a Learning Health System meeting at your HQ

How can pharma help create the Learning Health System? continued

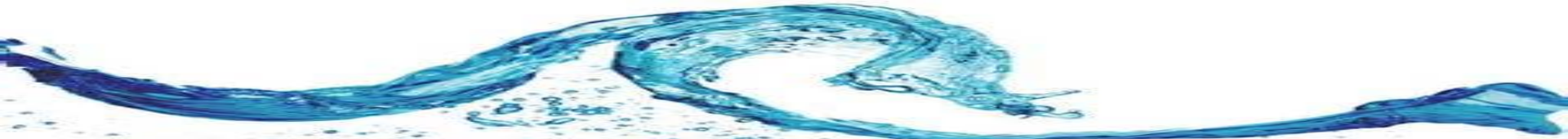
2. Help plan and build:

- Identify others in your organization who are interested; build a coalition in your organization to help progress the Learning Health System
- Dedicate staff capacity to engage and contribute to Learning Health System initiatives, projects, task forces
- Coordinate experts at your organization reviewing and commenting on the stakeholder tables (what needs to change so your organization can engage in the LHS?)
- Coordinate experts at your organization reviewing and commenting on the LHS value proposition

How can pharma help create the Learning Health System? continued

3. Spread the word – inside and out:

- Spread the word when your company endorses the LHS Core Values
- Share key LHS articles and white papers, etc. internally
- Present internally on the LHS
- Connect other initiatives you are involved in to the LHS
- Post about the LHS on your organization's social media sites
- Publish in *Learning Health Systems*



How can pharma help create the Learning Health System? continued

4. Learn and prepare:

- Attend LHS meetings
- Stay on top of published articles, books, and white papers on the LHS
- Inform your organization's strategies, initiatives and projects (LHS as future context)
- Prepare your organization for an operational Learning Health System

Watch out: systems thinking may have its own effect…
you may begin to form your own rapid learning loops internally

Preparing your pharma co for the Learning Health System

INITIATIVES	TIMEFRAMES	OBSTACLES / CHALLENGES	INFLUENCING FACTORS	DEPENDENCIES	PREREQUISITES	TECHNOLOGIES	REGULATIONS	FUNDING
• Adapt internal policies regarding sharing data and evidence	• 3 years total – 1 year for adoption	• Consensus around regulatory and communication regarding internal policies	• Pharma executives agreement	• Establish priority with Quality and Compliance organizations • Agreed standards to ensure a consistent level of quality of RWE is shared or when RWE is shared, the limitations are clearly shown	• Updated/clarified regulations on pharma communication of data, info, and evidence in LHS	• Minimal	•	• Internal to company
• Align on and adapt to LHS standards	• 4 years	• Big impact on processes if standards are not aligned	• Pharma executives agreement	• ESTEL establishing standards in cooperation with pharma	• ESTEL establishes standards and gap analysis • Executive advocate/sponsorship (may require sponsor initiative)	• Significant technology implications to update/change	•	• Internal to company

Preparing your pharma co for the Learning Health System continued

INITIATIVES	TIMEFRAMES	OBSTACLES / CHALLENGES	INFLUENCING FACTORS	DEPENDENCIES	PREREQUISITES	TECHNOLOGIES	REGULATIONS	FUNDING
• Increase speed of answering research questions (CT and RWE)	• ongoing	• Internal inefficiencies • Internal capability gap in RWA and RWE • Data lag for certain types of RWD (claims) • Barriers to access to linked data (claims, specialty EMR, mobile data) • Overall timelines for CT execution from design to enrollment to dissemination • Scientific publication is the only means to quickly share CT and RWE that is off-label but may be very important to LHS	• Is it regulatory? •	• Pharma company resourcing RWE capability development	•	• Collection of RCT measures in the context of clinical care/EMR network • Data warehouses that allow for seamless, rapid, and reliable linking across RWD types including data collected via web or mobile devices	• Update regulations on CTs	•
• Strengthen internal learning system	•	• Information overload • Lack of true reward system for continuous learning limits uptake • Employees span the globe • Potential conflict with initiatives that limit sharing of information beyond those with a clear need to know (e.g. Protect Lilly)	•	•	•	• Information system to efficiently scan and share knowledge corporately	•	•

Preparing your pharma co for the Learning Health System continued

INITIATIVES	TIMEFRAMES	OBSTACLES / CHALLENGES	INFLUENCING FACTORS	DEPENDENCIES	PREREQUISITES	TECHNOLOGIES	REGULATIONS	FUNDING
• Adapt internal safety surveillance and risk evaluation and management strategies	•	• Lack of nationally representative EMR data (there are initiatives ongoing with Truven claims)	•	•	•	•	•	•
• Adapt internal activities regarding understanding disease mechanism, progression, prevalence, and unmet need	•	• Knowledge is siloed by department • Inefficiency in knowledge transfer as molecules step through clinical development phases	•	•	•	• Information system to efficiently scan and share knowledge corporately	•	•
• Adapt internal CT planning and execution activities	•	• Adaptations are seen as barriers to timely regulatory submission • Operational issues associated with adaptive design not well understood and thus adaptive designs are not readily embraced	• FDA guidance on learning trials, pragmatic trials • FDA feedback at the indication/molecule level •	• Corporate embrace of adaptive trials • Reward teams for trials that result in greater knowledge rather than simply speed to submission	•	•	•	•
• Adapt internal activities regarding regulatory submission and inquiries (e.g., for ongoing benefit/risk assessments)	•	• B/R analyses viewed as potentially limiting access of medications to patients rather than increasing access (emphasis in risk over benefit)	•	•	• Standardized and automated report format to ease this frequent process for large cross-functional teams • Standards for what benefit/risk means	•	•	•

Preparing your pharma co for the Learning Health System continued

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• Senior executive support and sponsorship of engagement with LHS	•	• Potential skepticism as to the likelihood of LHS being developed in the US	•	•	• Education as to the benefits of LHS to pharma as well as the patient – clear business case for involvement	•	•	•
• Adapt internal activities regarding understanding product usage and effectiveness post-launch	•	• Access to RWD, especially OUS • RWE development capability limited • Comparative effectiveness perceived as a chance to lose. It's not required by the regulators, so do we go there? • Lack of access to real time RWD • Ability to quickly modify DLL in response to learning from the field	• Payers perception of the value of this information • Increase in product-specific RWE developed by other entities than the manufacturer	• Ability to holistically plan CT and RW evidence • Efficient means to incorporate learnings about the product from the LHS into ongoing research agenda	•	•	•	•
• Build and coordinate internal centralized capability for access to and governance over RWD	•	• Financial incentives for data vendors to enable this	• Unless RWD for research could be pre-competitive and shared	• Interoperability standards identified and consensus on them	•	• Interoperability tech • New techs to collect data around the patient (not just in contact with healthcare system)	•	•
• Develop internal platforms/infrastructure and tools to support use of RWD	•	• RWD challenges in general • Lack of easy to use data source agnostic tools	•	•	•	•	•	•
• Align policy engagements and activities with LHS	•	•	•	•	•	•	•	•

Preparing your pharma co for the Learning Health System continued

INITIATIVES	TIMEFRAMES	OBSTACLES / CHALLENGES	INFLUENCING FACTORS	DEPENDENCIES	PREREQUISITES	TECHNOLOGIES	REGULATIONS	FUNDING
• Adapt internal launch readiness activities	•	• Determined access to appropriate RWD for post-launch RWE prioritized as a key step for clinical development teams and as a performance measure for launch leader	•	• Ability to holistically plan CT and RW evidence • Discipline to regularly review and revise the RWE HEP	•	•	•	•
• Add/shift dedicated headcount to support LHS	•	•	•	•	•	•	•	•
• Develop strategies for value-based and indication-based contracting	•	•	•	•	•	•	•	• Internal to company
• Manage culture change toward a knowledge sharing system	•	•	• Reward structure	•	•	•	•	• Internal to company

What needs to change for the pharma *industry* to engage in the LHS?

INITIATIVES	TIMEFRAMES	OBSTACLES / CHALLENGES	INFLUENCING FACTORS	DEPENDENCIES	PREREQUISITES	TECHNOLOGIES	REGULATIONS	FUNDING
• Clarify rules of engagement regarding pharma communication	• ASAP (within 2 years)	• Industry must carefully follow regulations re communicating with patients, payers, and providers • Not a priority for regulatory bodies	• Regulatory statutes and guidance	• Policy alignment • Coordination across the industry	• Changes to (or increased clarity) to allow appropriate communication in LHS • Gap analysis of current rules versus end-state for FDA	• Minimal (data security and privacy)	• Need to adapt to allow engagement in LHS and global alignment around regulatory matters	• FDA's obligation to support
• Ensure appropriate access and increase transparency about access to and co-use of de-identified data for research	• PhrMA - Coordinate industry campaign around transparency – within 1 year after agreement	• Achieving trust and expanding informed consent for data usage • Data vendors have business incentive to block such access	•	•	• Articulate how industry appropriately uses de-identified data for research; increase transparency • Public trust and endorsement of de-identified data for co-use	• De-identification techs • Flexible and secure access techs (for patient control of data)	• HIPAA and other geographical policies regarding clinical data for research	•
• Clarify IP protection	• IP Group	• Balance between sharing and openness and need to protect IP	• Industry needs to provide guidance	• US Congressional action may limit enthusiasm from Pharma	• Trusted policies for IP protection in the LHS	•	•	•
• Decide as pharma industry what is pre-competitive	• Guidance from TransCelerate team on timeframe to establish	• Gain consensus across industry	• Ala? TransCelerate • TransCelerate outside of CTs	•	• Trust • Mechanism for coordination of pre-competitive space	•	•	•
• Continue to work across healthcare industry to standardize approaches to real world analytics	•	• Gain consensus across healthcare ecosystem on RWA algorithms	• RWE Team to validate timeline •	• Endorsement of standards by key professional societies, regulatory agencies	• Need for flexible algorithms to define evidence based understanding of RWA	• Real world analytics technologies	•	•

Thank you!

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