DIGITAL THERAPEUTICS ALLIANCE

AUGUST 2023

Progress Report: DTx Integration & Workflow

PURPOSE

Provide an update to the next steps identified in the Report released February 2023. That report identified gaps or pain points in the integration and workflow of DTx products in the U.S. healthcare system and outlined the next steps to optimize the experience for clinicians and patients.

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ABOUT DTA

Digital Therapeutics Alliance (DTA) is a trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics. As the leading international organization on digital therapeutic thought leadership and education, DTA provides policymakers, payors, clinicians, and patients with the necessary tools to evaluate and utilize DTx products.

MISSION

Broaden the understanding, adoption, and integration of clinically-evaluated digital therapeutics for patients, clinicians, payors, and policymakers through education, advocacy, and cross-industry collaboration.

Executive Summary

Digital therapeutics (DTx) have potential to fill gaps in care for people and their families across the world. As a new category of medicine, one of the first barriers is the challenge of integration into the traditional healthcare system so that patients can receive access in a way that is convenient and consistent for them. This effort takes significant collaboration amongst diverse stakeholders across the complex healthcare system in the United States.

These stakeholders include policymakers from governing bodies, clinician and provider systems, health plans, pharmacies, DTx product manufacturers, and patients. However, there are many healthcare partners working behind the scenes to make it all work including pricing compendias and EHR vendors.

Six months ago, in February 2023, DTA and NCPDP released a report outlining the workflow and integration for prescription digital therapeutic products. The report identified pain points, considerations to solve for, and next steps in solving for those pain points. DTA has continued to work with collaborators across the healthcare ecosystem and with NCPDP Task Groups to address pain points one by one. This update serves as a progress report for what has been accomplished and what is in progress.

Additionally, DTA and its Members expanded on the scope of February's report and have drafted the outline to integrate nonprescription digital therapeutic products in the healthcare system. Both prescription and nonprescription models serve important roles to improve health for people and their families.

We are proud to solve barriers to patient access and invite you to join us in our efforts.

Andy Molnar
Chief Executive Officer
Digital Therapeutics Alliance

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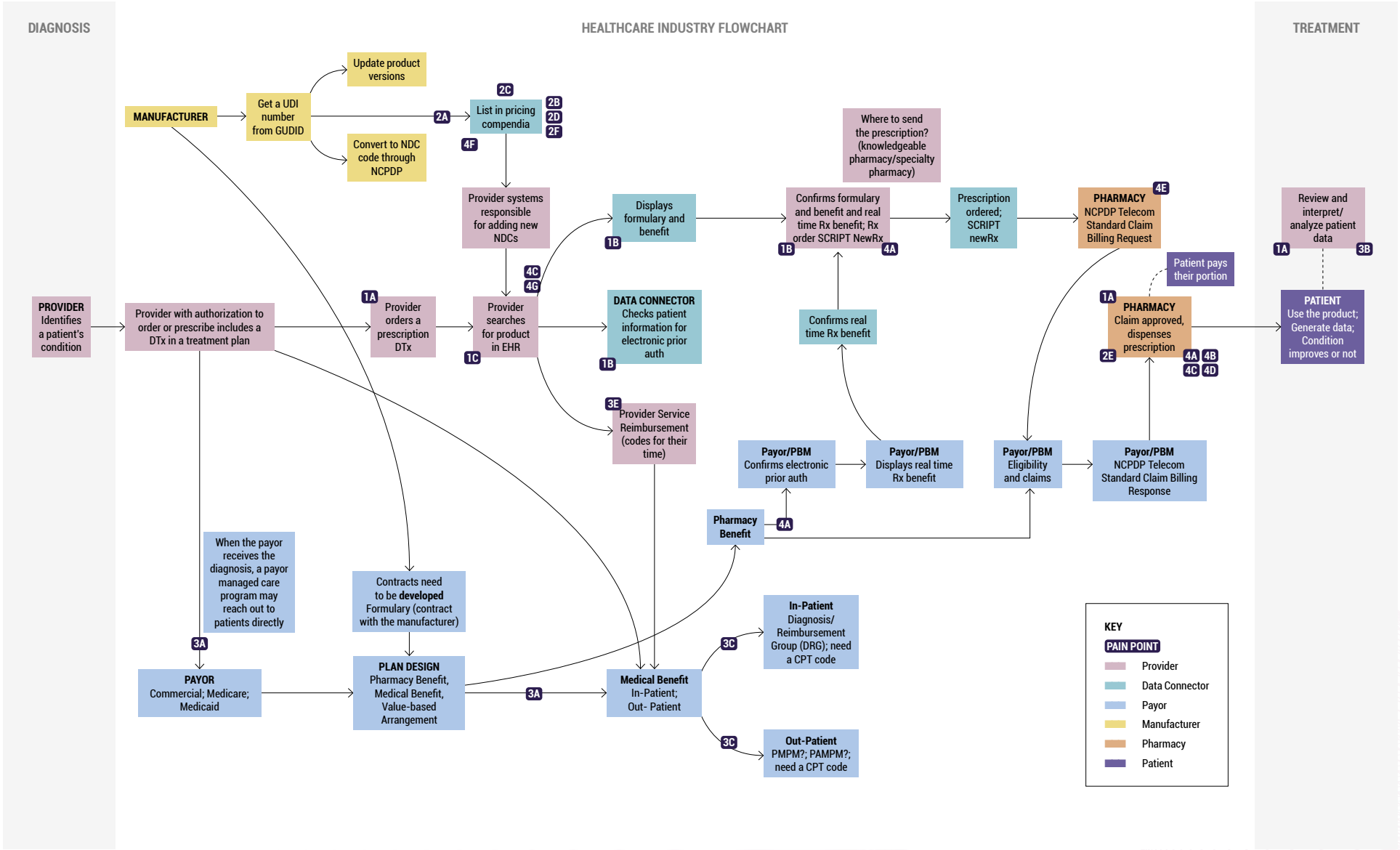
Review of Flowchart with Pain Points from Original Report



CLICK HERE TO DOWNLOAD THE ORIGINAL REPORT

Updates to Address Pain Points

Pain Point	Update	Next Steps
PROVIDER PERSPECTIVE		
1A The scope of professionals who are involved is not clearly defined.	» In order to establish scope of work, clinicians of all types need to understand and trust the products they are working with. To meet this need, USP is aligning specialized committees to address the gaps in standards intended to approve quality metrics with prescribed products. A series of informational meetings is currently taking place and will be ongoing.	
1C Provider systems' EHR integrations are not optimized for DTx products.	Two key topics we've explored in the task force thus far as it relates to how the EHR can be enabled to support PDT products: » Understand how PDTs are handled with the compendia vendors and how compendia are managed by providers. The compendia is the first step to understanding the PDT product and it is from here the product will be uploaded in the EHR to be leveraged by providers. » Once a PDT product is available in the EHR, it's not turnkey that the product becomes available, understood, and adopted by the provider teams. » We've documented considerations and known workflow for how compendia is brought into the EHR and how orderables are created. » Compendia are pulled into the EHR via an SFTP load. This requires an analyst to run a job to do the import. Systems may be doing this on a weekly or quarterly basis » Often there will be multiple files from the compendia vendors that need to be pulled in—dosing information, interactions, etc. Information may be stored in different files and devices aren't always included in the file and may have to be pulled in separately. This is important because some PDTs may be classified under devices. » Med Orderables must be built in the EHR and associated with a product from the Compendia » EHR analysts will work with Revenue Cycle to ensure orders can appropriately drop a charge.	» Address the precursors to the order and the downstream impacts of order. For example: screening tools in place to determine fit for the patient, impact to medication reconciliation workflows, impact to revenue cycle workflows » Work closely with colleagues on non-prescription digital therapeutic products as we suspect there will be overlap for workflow and EHR considerations

Pain Point	Update	Next Steps
DATA CONNECTOR PERSPECTIVE		
2A DTx products need a uniform way to be codified in the Compendium so that it can be used by providers, payors, and pharmacies.	In partnership with NCPDP and several Compendia, DTA released a Rx DTx Compendia Submission & Tracking checklist for digital therapeutic products. (see page 8 for Submission Requirements)	Socialize Compendia Submission Checklist with all compendia to provide education around how to include DTx into their lists with the aim to have all Compendia include DTx products.
2B Not all Compendia will load DTx products.	Currently, 5 out of 12 compendia are listing DTx products.	Socialize Compendia Submission Checklist with all compendia to provide education around how to include DTx into their lists with the aim to have all Compendia include DTx products.
2C There needs to be a way for Compendia to track product versions.	Through interviews and discussions with compendia and manufacturers, the following best practice was agreed upon: *Compendia must be notified when an update is significant enough to require a change in UDI. It is at the discretion of each compendia, their editorial policy and ability as to whether products can be linked.*	Socialize the version tracking best practice with Compendia and DTx manufacturers. Another action is to identify a process for product recalls for digital products.
PAYOR PERSPECTIVE		
3A There is a lack of and inconsistent coverage by health plans and CMS.	» The Access to Prescription Digital Therapeutics Act was introduced into Congress on March 8, 2023. Since then, 18 House Co-sponsors and 4 Senate Co-sponsors have signed onto the bill. DTA and other groups and companies continue to advocate for this important piece of legislation that would create a benefit category for CMS to cover prescription software as a medical device. » DTA was awarded a grant from the NCPDP Foundation to develop outlines for Pharmacy and Medical Benefit pathways and rationale for why a payor may choose which pathway is best for them. This report will be completed November 2023.	» DTA and partners will continue to advocate for CMS coverage for digital therapeutic products through legislation and the addition of new HCPCS codes. » The pharmacy and medical benefit guidance document will be released by the end of 2023.

Pain Point	Update	Next Steps
PHARMACY PERSPECTIVE		
4C There is a limited distribution network.	» After review of the NCPDP paper on Facilitating Access to Specialty Products, the group determined that the paper is relevant and serves as a best practice for DTx. in summary, a high quality, limited distribution network is better than a low quality, wider distribution network. » Currently, some companies are serving as their own patient support service provider and some companies are working with a specialty pharmacy. Following interviews with specialty pharmacies, it was determined that there needs to be an economic benefit for them to provide patient support services.	» Identify options for specialty pharmacies to receive payment for patient services. » Determine if Real Time Benefit checks can support DTx distribution. » Align relevant stakeholders on best practices for distribution.

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Rx DTx Compendia Submission & Tracking

Similar to pharmaceuticals and medical devices, digital therapeutic products need to be included in pricing compendia in order to be integrated into the full healthcare system from provider to payor to pharmacy workflows.

Submission timelines vary but generally take between several days to several weeks if approved.

This checklist serves as a guide to compendia requirements but each compendia is subject to their individual policies.

Required Documents

- ☐ GS1 Company Registration:
  - ○ Client must be registered with GS1
    - ○ Company will be visible on GS1 Website (https://gepir.gs1.org/)
    - ○ Acquire a Company Prefix
      - ○ If the company has an FDA Labeler Code, ensure it is incorporated into the GS1 Company Prefix when requesting Company Prefix (https://www.gs1.org/standards/id-keys/company-prefix)
- ☐ UDI product creation: Once the GS1 company prefix has been established, you must:
  - ○ Create your UDI/GTIN product identifier(s)
  - ○ Update artwork files with UDI/GTIN details (if applicable)
- ☐ GUDID product upload:
  - ○ Product must be listed with the GUDID (NLM database)
    - ○ Submit to GUDID: https://www.fda.gov/medical-devices/global-unique-device-identification-database-gudid/submit-data-gudid
    - ○ Access GUDID: https://accessgudid.nlm.nih.gov/
    - ○ This task will be completed by the Labeler
- ☐ FDA Letter of Designation:
  - ○ Software Only
  - ○ Device Only
  - ○ Includes Both
    - ○ List components (if applicable)

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Rx DTx Compendia Submission & Tracking

- ☐ Product Labeling:
  - ○ Brand Name
  - ○ Label Name (Product Name & Attributes)
  - ○ Barcode details and image(s)
    - ○ GTIN12
    - ○ GTIN14
    - ○ UDI
- ☐ Product Information:
  - ○ Operating system: iOS, android, or both
  - ○ Instruction for use (IFU)
  - ○ Clinical indication information (if applicable)
    - ○ Age range
    - ○ Duration of therapy
  - ○ Flyers/posters
  - ○ Users manual
  - ○ Image of product
  - ○ Identify the intended use (for classification purposes)
  - ○ Identify all Product Codes/SKUs
  - ○ Identify if Prescription Use Only (Rx or OTC)
  - ○ Pricing Information Required (Price Type to be submitted)
  - ○ Launch Date
- ☐ Authorized Distributors:
  - ○ Is Pharmacy involved (adjudication/processing)?
  - ○ Limited Distribution Pharmacy? (y/n)
- ☐ Submission Form (sample):
  - ○ Company Name
  - ○ Contact Name
  - ○ Contact Telephone Number
  - ○ Contact E-mail
  - ○ Product Code ID
    - ○ GTIN/UDI/UPC Number
    - ○ NHRIC (if applicable)
  - ○ Product Name
  - ○ Package Size
  - ○ Dosage Form
    - ○ Application
    - ○ VR Headset
    - ○ Kit
    - ○ Other
  - ○ Rx or OTC
  - ○ Wholesale Acquisition Cost
  - ○ Direct Price
  - ○ Suggested Average Wholesale Price
  - ○ Effective Date
  - ○ Product Physical Description if not provided in package insert or label (if applicable)

Version Tracking: *Compendia must be notified when an update is significant enough to require a change in UDI. It is at the discretion of each compendia, their editorial policy and ability as to whether products can be linked.*

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Nonprescription DTx Integration & Workflow

During the development of the report released in February 2023, it was determined that the scope of digital therapeutics was too large to capture at that time. There are prescription and nonprescription models, models that include a hardware component, some that are software only, and some that compliment a pharmaceutical. Because of this wide variety, we limited the scope at that time to prescription digital therapeutics.

This spring, we added a Nonprescription Integration & Workflow task group and initiative to outline what is in place now and where the pain points take place with nonprescription models of digital therapeutic products.

DTA identified several key stakeholders that were well positioned to draft flow charts for the integration and workflow as they understood, noting the gaps and pain points that existed. These groups included:

» DTA Member Manufacturers of products

» DTA advisors including payors, clinicians, and board members

Scope and Key Assumptions

SCOPE: The scope of the project addresses the pathways for nonprescription digital therapeutic products in the U.S.

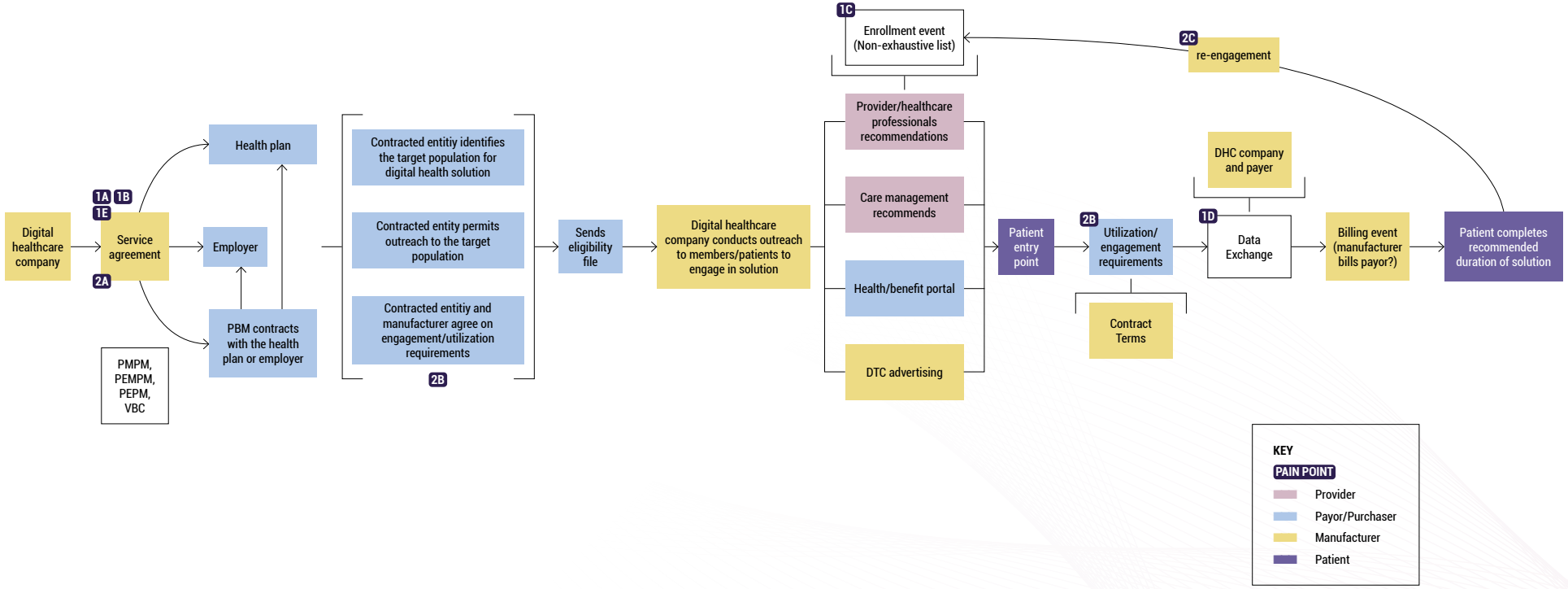
FDA oversight includes:

» Enforcement discretion

» Class II Medical Device—OTC

DTA convened a task group to develop the flow chart and to outline pain points and considerations. Next steps are to address these pain points within the task groups in the order of criticality, as defined by participants.

NONPRESCRIPTION DTX INTEGRATION & WORKFLOW FLOWCHART



Pain Point	Update	Next Steps
PAYOR PERSPECTIVE		
1A Manufacturers are not easily able to identify the key decision maker in payer organization.	In order to establish scope of work, clinicians of all types need to understand and trust the products they are working with. To meet this need, USP is conducting research and engaging stakeholders to address the gaps in standards intended to approve quality metrics with prescribed products. The outcomes of a recent DTx panel involving experts across industry, healthcare and academia are currently being published while ongoing research continues.	Link to provide commentary to published summary of DTx Panel at USP will be available to the public shortly.
1B Product evaluation is unclear in the payer organization.	Use of a standardized assessment.	Socialize DTA's value guide and evaluation toolkit.
1C Enrollment Event/Getting members on the DHC solution is inconsistent.	Alignment on population and agreement on joint promotion between (health plan/employer/manufacturer) can maximize uptake.	Outline a framework of strategies that may be effective.
1D Integration with other payer solutions.	Does the new data generated and captured by the DHC solution aid with payer needs—whether that information is integrated in care management, supplied to providers' EHR, etc. Can the DHC solution synergize with payers current efforts of care gap closure?	Define feedback loop in conjunction with prescription workflow group.
1E Security assessments for health systems or any customer at a group level are not standardized.	Aggregate the top asked questions on security assessments (HITECH, SOC2, penetration tests, etc) and have the information ready to fill out. Most groups have their own and will not accept a template from a vendor.	» Research of security assessment forms and aggregate commonalities of questions asked. » List nuance questions to be prepared for. » Find commonalities by demographic (Clinical Trials, Health Systems, Employer groups, etc.)

Pain Point	Update	Next Steps
MANUFACTURER PERSPECTIVE		
2A Alignment on Contracting.	There are many parts to a service agreement (contract)—streamlining on data sharing, risk components, terms and conditions and rates/cost can delay execution.	» Illustrate contract timelines. » Create service agreement template(s) taking into consideration differences between public payer, commercial payer, regional payer.
2B Definition of engagement is inconsistent.	Aligning on key examples for patient/member engagement with DHC solution: what are standardized examples that can apply across companies and be aligned by payers?	Determine commonalities regarding patient engagement via manufacturer survey/interview.
2C Continued engagement from end users drops off putting the product's value at risk.	» Is the digital solution optimized for all customers or will there be a line of who will have access and who won't. Example: device types have various storage spaces. » Noom's app can take up to 2G's of memory space on an average mobile device. An app that large will be the first to be deleted as the general population prioritizes entertainment.	» Create Evaluation of natively built applications for memory size on most devices. » Optimize the way content is stored and received. Limit features that increase the storage space needed for device downloaded experiences.

Acknowledgements

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Services
USP
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Xealth

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