

ATTACHMENT C **DSRIP Planning Protocol**

I. Preface

On January 9, 2017, the Centers for Medicare & Medicaid Services (CMS) approved Washington State's request for a section 1115(a) Medicaid demonstration entitled *Medicaid Transformation Project* demonstration (hereinafter MTP or "demonstration"). Part of this demonstration is a Delivery System Reform Incentive Payment (DSRIP) program, through which the state will make performance-based funding available to regionally-based Accountable Communities of Health (ACH) and their partnering providers. The demonstration is currently approved through December 31, 2021.

The Special Terms and Conditions (STC) of the demonstration set forth in detail the nature, character, and extent of federal involvement in the demonstration, the state's implementation of the expenditure authorities, and the state's obligations to CMS during the demonstration period. The DSRIP requirements specified in the STCs are supplemented by two attachments to the STCs. The DSRIP Planning Protocol (this document, Attachment C) describes the ACH Project Plans, the set of outcome measures that must be reported, transformation projects eligible for DSRIP funds, and timelines for meeting associated metrics.

This protocol is supplemented by a Project Toolkit and Project Measure and Performance Table. The toolkit provides additional details and requirements related to the ACH projects and will assist ACHs in developing their Project Plans.

In accordance with STC 34, the state may submit modifications to this protocol for CMS review and approval. Any changes approved by CMS will apply prospectively unless otherwise specified by CMS.

II. ACH Project Plan Requirements

a. Introduction

ACH Project Plans will provide an outline of the work that an ACH, through its partnering providers, will undertake. The plans must be developed in collaboration with community stakeholders and be responsive to community needs. The plans will provide details on how the selected projects respond to community-specific needs and further the objectives of the demonstration. The

plans also will describe the ACH's capacities, composition and governance structure. In order to be eligible to receive DSRIP incentive payments, an ACH must have an approved Project Plan.

There are three steps for ACH Project Plan approval:

1. ACHs must satisfy a two-phase certification process that will confirm the ACHs are prepared to submit Project Plan applications. Completion of each phase will qualify the ACHs for Project Design funding. Certification criteria will be set forth by the state, and ACHs will submit both phases of certification information to the state within the required time frames. The state will review and approve each certification phase prior to distribution of Project Design funds for that phase.
 - a. Phase 1 certification requirements must be submitted to the state by May 15, 2017.
 - b. Phase 2 certification requirements must be submitted to the state by August 14, 2017.

Certification criteria are described further below.

2. ACHs must develop and submit a Project Plan application for approval. The components of the Project Plan are described in STC 36 and further detailed in this protocol. Completed Project Plan applications are due to the state by November 16, 2017.
3. The state and its contracted Independent Assessor will evaluate and (if appropriate) approve ACH Project Plans. ACHs with approved Project Plans are eligible to receive performance-based incentive payments. The state and the Independent Assessor will approve Project Plans as early as November 20, 2017, and no later than December 22, 2017.

The state will develop and post a draft Project Plan Template for public feedback prior to releasing a final version. Design funds attached to each certification phase will support ACHs as they address specific requirements and submit their Project Plans. As ACHs develop Project Plans, they must solicit and incorporate community and consumer input to ensure that Project Plans reflect the specific needs of the region. After the Project Plans are submitted to the state, they will be reviewed by an Independent Assessor contracted by the state. The Independent Assessor will review and make recommendations to the state for approval of Project Plans. The state must approve of Project Plans in order to authorize DSRIP incentive funding. Project Plans may be subject to additional review by CMS.

b. ACH Certification Criteria

The certification process is intended to ensure that each ACH is prepared to serve as the lead entity and single point of accountability to the state for the transformation projects in its region. The certification application solicits information to ensure that: (a) the ACH is qualified to fulfill the role of overseeing and coordinating regional transformation activities; (b) the ACH meets the composition standards outlined in STC 23; and (c) the ACH is eligible to receive project design funds. There are two phases to the certification process. According to a timeline developed by the state, each ACH must complete both phases and receive approval from the state before submitting a Project Plan application.

Phase 1 Certification: Each ACH must demonstrate compliance and/or document how it will comply with state expectations in the following areas, at a minimum:

1. Governance and Organizational Structure, including compliance with principles outlined in STC 22 and decision-making expectations outlined by the state.
2. Initiation or continuation of work with regional Tribes, including adoption of the Tribal Engagement and Collaboration Policy or alternate policy as required by STC 24.
3. Community and Stakeholder Engagement to demonstrate how the ACH is accountable and responsive to the community.
4. Budget and funds flow, including how design funds will support project plan development.
5. Clinical capacity and engagement to demonstrate engagement and input from clinical providers.
6. Other requirements as the state may establish.

Phase 2 Certification: Each ACH must demonstrate that it is in compliance with state expectations in the following areas, at a minimum:

1. Governance and Organizational Structure, including compliance with principles outlined in STC 22 and decision-making expectations outlined by the state. ACHs will describe whether any developments or adjustments have occurred since Phase 1 Certification.
2. Tribal Engagement and Collaboration describing specific activities and events that further the relationship between the ACH and Tribes.
3. Community and Stakeholder Engagement to describe concrete actions that have occurred since Phase 1 Certification. Provide details for how

- the ACH will satisfy public engagement requirements for Project Plan development outlined in STC 23.
4. Budget and funds flow to summarize strategic use of funding and decision making processes regarding incentive funding distribution.
 5. Data-informed decision making strategies, including processes for applying available data to project selection and implementation planning.
 6. Transformation project planning to describe progress on project selection processes.
 7. Other requirements as the state may establish.

c. *ACH Project Plan Requirements*

As part of this demonstration, each ACH and its regional participating providers will be responsible for implementing a set of projects selected from the Project Toolkit. The Project Plan:

- Provides a blueprint of the work that each region, coordinated by the ACH, will undertake through the implementation of these projects.
- Explains how the regional work responds to community-specific needs, relates to the mission of the ACH, and furthers the objectives of the demonstration.
- Provides details on the ACH's composition and governance structure, specifically any adjustments to refine the model based on initial lessons learned.
- Demonstrates ACH compliance with the terms and conditions of participation in the demonstration.
- Incorporates the voice and perspective of the community and consumers through outreach and engagement.

Each ACH will submit a Project Plan to the state for review. The Project Plans will be used by the state to assess ACH preparedness in planning and implementing its local demonstration program and the regional alignment with the demonstration's overall objectives and requirements. The state's contracted Independent Assessor will review and evaluate Project Plans and make recommendations to the state for approval/remediation of each Plan. In addition, commitments made by an ACH in its Project Plan must be consistent with the terms of a contract between the state and the ACH, outlining the requirements and obligations of the ACH as the lead and other partnering providers in the ACH in order to be eligible to receive DSRIP incentive funding.

The Project Plan Template will provide a structured format and outline the information required to be submitted by each ACH as part of its Project Plan. The template will be divided into two main sections and will include scoring criteria. Section I will focus on how the ACH, through its partnering providers, is being directly responsive to the needs and characteristics of the community it serves. It will include details regarding the ACH's overall programmatic vision, composition, and decision-making processes. Section II will ask ACHs to provide detailed project-specific plans. The state may add additional requirements to the Project Plan application in addition to what is outlined below.

The categories for Section I of the Project Plan template will include:

1. *ACH Theory of Action and Alignment Strategy*: Rationale explaining how the ACH plans to improve the quality, efficiency, and effectiveness of care processes in its community.
2. *Governance*: Description of how the ACH complies with the state's governance and decision-making expectations.
3. *Regional Health Needs Inventory*: Description of how the ACH used available data to identify target populations and ensure that project selection responds to community-specific needs, aims to reduce health disparities, and furthers the objectives of the demonstration.
4. *Community and Consumer Engagement and Input*: Evidence of public input into the project plans, including consumer engagement. ACHs must demonstrate that they solicited and incorporated input from community members and consumers. The plan must also describe the processes the ACHs will follow to engage the public and how such engagement will continue throughout the demonstration period.
5. *Tribal Engagement and Collaboration*: Demonstration that the ACH has complied with the Tribal Engagement and Collaboration requirements.
6. *Budget and Funds Allocation*: Description of how decisions about the distribution of funds will be made, the roles and responsibilities of each partner in funds distribution and a detailed budget for the remaining years of the demonstration.
7. *Value-based Payment Strategies*: Description of the regional strategies to support attainment and readiness of statewide VBP targets.

For each selected project, Section II requires, that ACHs provide details regarding:

1. *Partnering Organizations*: Description of the partnering providers, both traditional and non-traditional, that have committed to participate in projects. Partnering providers must serve and commit to continuing to serve the Medicaid population. ACHs must ensure that together, these partnering providers serve a significant portion of Medicaid covered lives in the region and represent a broad spectrum of care and related social services that are critical to improving how care is delivered and paid for. Additional details on recommended implementation partners will be provided in Project Toolkit guidance documents.
2. *Relationships with Other Initiatives*: The ACH will attest to securing descriptions of any initiatives that its partnering providers are participating in that are funded by the U.S. Department of Health and Human Services and any other relevant delivery system reform initiatives currently in place and ensuring these projects are not duplicative of DSRIP projects. In DY 2, partnering providers will be required to provide descriptions and attest that DSRIP projects are not duplicative of other funded projects and do not duplicate the deliverables required by the former project(s). If projects are built on one of these other projects, or represent an enhancement of such a project, that may be permissible but the ACH will be required to explain how the DSRIP project is not duplicative of activities already supported with other federal funds.
3. *Monitoring and Continuous Improvement*: Description of the ACH's plan for monitoring project implementation progress and continuous improvement or adjustments in alignment with Section V (Process for ACH Project Plan Modification).
4. *Expected Outcomes*: Description of the outcomes the ACH expects to achieve in each of the project stages, in alignment with the metrics and parameters provided by the state.
5. *Sustainability*: Description of how the projects support sustainable delivery system transformation for the target population.
6. *Regional Assets, Anticipated Challenges and Proposed Solutions*: Description of the assets that the ACH and partnering providers bring to the delivery system transformation efforts, and the challenges or barriers they expect to confront in improving outcomes and lowering costs for the target populations. For identified challenges, the ACH must describe how

it expects to mitigate the impact of these challenges and what new capabilities will be required to be successful.

7. *Implementation Approach and Timing:* Explanation of the planned approach to accomplishing each set of required project milestones for each of the selected projects.

III. Project Toolkit

a. Overview of Project Categories

Each ACH, through its partnering providers, is required to implement at least four transformation projects and participate in statewide capacity building efforts to address the needs of Medicaid beneficiaries. These projects will be spread across the following three domains:

1. Health Systems and Community Capacity Building
2. Care Delivery Redesign (at least two projects)
3. Prevention and Health Promotion (at least two projects)

The Domains, and the strategies defined within each Domain, are interdependent. Domain 1 is focused on systemwide planning and capacity-building to reinforce transformation projects. Domain 1 strategies are to be tailored to support efforts in Domain 2 and Domain 3; projects in Domain 2 and Domain 3 integrate and apply Domain 1 strategies to the specified topics and approaches.

ACHs will develop detailed implementation plans. As described in Section IV, project progress will be measured based on state-defined milestones and metrics that track project planning, implementation, and sustainability.

b. Description of project domains

i. Health Systems and Community Capacity Building

This domain addresses the core health system capacities to be developed or enhanced to transition the delivery system according to Washington's Medicaid Transformation demonstration. Domain 1 does not outline individual projects, but rather three required focus areas to be implemented and expanded across the delivery system, inclusive of all provider types, to benefit the entire Medicaid population. The three areas of focus are: financial sustainability through value-based payment, workforce, and systems for population health management. Each of these areas will need to be addressed progressively throughout the five-year

timeline to directly support Domain 2 and Domain 3 transformation project success.

ii. Care Delivery Redesign

Transformation projects within this domain focus on innovative models of care that will improve the quality, efficiency, and effectiveness of care processes. Person-centered approaches and integrated models are emphasized. Domain 2 includes one required project and three optional projects. ACHs will be required to select at least one of the optional projects for a minimum of two Domain 2 projects in total.

iii. Prevention and Health Promotion

Transformation projects within this domain focus on prevention and health promotion to eliminate disparities and achieve health equity across regions and populations. Domain 3 includes one required project and three optional projects. ACHs will be required to select at least one of the optional projects for a minimum of two Domain 3 projects in total.

Table 1. Menu of Transformation Projects

#	Project	Description
Health Systems and Community Capacity Building		Foundational activities that address the core health system capacities to be developed or enhanced to transition the delivery system in accordance with the demonstration's goals and transformation objectives.
Financial sustainability through value-based payment		Paying for value across the continuum of care is necessary to ensure the sustainability of the transformation projects undertaken through this demonstration. A transition away from paying for volume may be challenging to some providers, both financially and administratively. As not all provider organizations are equipped at present to successfully operate in these payment models, providers may need assistance to develop additional capabilities and infrastructure.
Workforce		The health services workforce will need to evolve to meet the demands of the redesigned system of care. Workforce transformation will be supported through the provision of training and education services, hiring and deployment processes, and integration of new positions and titles to support transition to team-based, patient-centered care and ensure the equity of care delivery across populations.

Systems for population healthmanagement	<p>The expansion, evolution, and integration of health information systems and technology will need to be supported to improve the speed, quality, safety, and cost of care. This includes linkages to community-based care models. Health data and analytics capacity will need to be improved to</p>
	<p>support system transformation efforts, including combining clinical and claims data to advance VBP models and to achieve the triple aim.</p>
Care Delivery Redesign	<p>Strategies that focus on innovative models of care to improve the quality, efficiency, and effectiveness of care processes. Person-centered approaches and integrated models are emphasized.</p>
2A	<p>Bi-directional integration of physical and behavioral health through care transformation</p> <p>The Medicaid system aims to support person-centered care that delivers the right services in the right place at the right time. Primary care services are a key gateway to the behavioral health system, and primary care providers need additional support and resources to screen and treat individuals for behavioral health care needs, provide or link with appropriate services, and manage care. Similarly, for persons not engaged in primary care services, behavioral health settings can be equipped to provide essential primary care services. Integrating mental health, substance use disorder, and primary care services has been demonstrated to deliver positive outcomes and is an effective approach to caring for people with multiple health care needs. Through a whole-person approach to care, physical and behavioral health needs will be addressed in one system through an integrated network of providers, offering better coordinated care for patients and more seamless access to the services they need. This project will advance Healthier Washington's initiative to bring together the financing and delivery of physical and behavioral health services, through managed care organizations, for people enrolled in Medicaid.</p>

2B	Care coordination	<p>Care coordination is essential for ensuring that children and adults with complex health service needs are connected to the evidence-based interventions and services that will improve their outcomes.</p> <p>Appropriately coordinated care is especially important for high-risk populations, such as those living with chronic conditions, those impacted by the social determinants of health such as unstable housing and/or food insecurity, the aging community, and those dependent on institutionalized settings. Communities are challenged to leverage and coordinate existing services, as well as establish new services to fill gaps. Without a centralized approach to “coordinating the coordinators,” a single person might be assigned multiple care coordinators who are unaware of one another, potentially provide redundant services, and risk creating confusion for the individual.</p>
2C	Transitional care	<p>Points of transition out of intensive services/settings, such as individuals discharged from acute care, inpatient care or from jail or prison into the community are critical intervention points in the care continuum.</p> <p>Transitional care services provide opportunities to reduce or eliminate avoidable admissions, readmissions and jail use.</p> <p>Individuals discharged from intensive settings may not have a stable environment to return to or may lack access to reliable care.</p> <p>Transitions can be especially difficult on beneficiaries and caregivers when there are substantial changes in</p>

		<p>medications or routines or an increase in care tasks. This project includes multiple care management and transitional care approaches.</p>
2D	Diversion interventions	<p>Diversion strategies provide opportunities to re-direct individuals away from high-cost medical and legal avenues and into community-based health care and social services that can offer comprehensive assessment, care/case planning and management to lead to more positive outcomes. This strategy promotes more appropriate use of emergency care services and also supports person-centered care through increased access to primary care and social services, especially for medically underserved populations.</p>
	Prevention and Health Promotion	<p>Projects focus on prevention and health promotion to eliminate disparities and achieve health equity across regions and populations.</p>

3A	Addressing opioid usepublic health crisis	The opioid epidemic affects communities, families, and overwhelms law enforcement, health care and social service providers. Opioid use disorder is a devastating and life-threatening chronic medical condition and access to treatments that support recovery and access to lifesaving medications to reverse overdose needs to be improved. This project will support strategies focused on addressing prevention, treatment, overdose prevention and recovery supports aimed at supporting whole-person health
3B	Reproductive and maternal/child health	Focusing on the health of women and children is a primary focus for the Medicaid program as Medicaid funds more than half of the births in the state and provides coverage to more than half of Washington's children. This project focuses on ensuring access to ongoing women's health care to improve utilization of effective family planning strategies. It further focuses on providing mothers and their children with home visits that have been demonstrated to improve maternal and child health. Home visitors work with the expectant or new mother in supporting a healthy pregnancy, by recognizing and reducing risk factors, promoting prenatal health care through healthy diet, exercise, stress management, ongoing well-woman care, and by supporting positive parenting practices that facilitate the infant and young child's safe and healthy development. Child health promotion is a state priority to keep children as healthy and safe as possible, which includes parents accessing timely and routine preventative care for children, especially well-child screenings and assessments.
3C	Access to oral healthservices	Oral health impacts overall health and quality of life, and most oral disease is preventable. Oral disease has been associated with increased risk for serious adverse health outcomes. Increasing access to oral health services for adults provides an opportunity to prevent or control the progression of oral disease, and to reduce reliance on emergency departments for oral pain and related conditions. This project focuses on providing oral health screening and assessment, intervention, and referral in the primary care setting, or through the deployment of mobile clinics and/or portable

		equipment. The project seeks to leverage the primary care workforce, andto strengthen relationships between primary care and dental providers, through stronger referral networks, improved communications, and shared incentives.
3D	Chronic disease prevention and control	Chronic health conditions are prevalent among Washington's Medicaid beneficiaries, and the number of individuals with or at risk for chronic disease is increasing. Disease prevention and effective management is critical to quality of life and longevity. Many individuals face cultural, linguistic and structural barriers to accessing quality care, navigating the health care system, and understanding how to take steps to improve their health. Improving health care services and health behaviors is only part ofthe solution. Washington State recognizes the impact that factors outside the health care system have on health and is committed to a "health in all policies" approach to effective health promotion and improved treatment of disease. The Chronic Disease Prevention and Control Project focuses on integrating health system and community approaches to improve chronic disease management and control.

IV. Project Stages, Milestones, and Metrics

a. Overview

In accordance with STC 35, over the duration of the demonstration, the state will shift accountability from a focus on rewarding achievement of progress milestones in the early years of the demonstration to rewarding improvement on performance metrics in the later years of the demonstration. During Years 2, 3 and 4, ACHs will be required to report against several progress milestones for each project, as described further below and as detailed in the Project and Metrics Specification guide. These progress milestones are, by definition, 'pay-for-reporting' or 'P4R,' since ACHs will be rewarded based on reported progress. Project progress milestones are defined in the Project Toolkit, specific to each project focus, and organized into three core categories: project planning milestones, project implementation progress milestones, and scale and sustain milestones.

To monitor performance, ACHs will be accountable for achieving targeted levels of improvement for project-specific outcome measures. These measures are primarily "pay-for-performance," or "P4P," since ACHs are only rewarded if

defined outcome metric targets are achieved. However, a subset of these measures will be rewarded on a P4R basis for reasons that include: to allow ACHs time for project implementation activities; to allow time to establish necessary reporting infrastructure; and to allow for the testing of new, innovative outcome measures for project areas where there is a lack of nationally-vetted, widely used outcome measures. Performance metrics are consistent with the objectives of the demonstration as outlined in STC 30.

Table 2 below summarizes the different categories of measures. Each category is described in further detail below.

Table 2. Demonstration Milestone/Metric Categories

Milestone/Metric Type	DY1 (2017)	DY2 (2018)	DY3 (2019)	DY4 (2020)	DY5 (2021)	DY6 (2022)
Project Progress Milestones	NA	P4R	P4R	P4R	NA	NA
Performance Metrics	NA	NA	P4R/P4P	P4R/P4P	P4R/P4P	P4R/P4P
Value-based Payment Metrics	P4R/P4P	P4R/P4P	P4R/P4P	P4R/P4P	P4P	N/A ¹

b. *Progress Milestones (Capacity Building Elements, Progress/Planning Milestones, and Metrics)*

During demonstration Year 1, each ACH will be responsible for the development, submission and approval of a Project Plan application. As part of the Project Plan application, the ACH will provide a timeline for implementation and completion of each project, in alignment with progress milestones specified in the Project Toolkit and accompanying documents. General categories of progress milestones required to be completed for each project include:

- Identify target population and assess partnering providers' capacity to fulfill project requirements. Collectively, partnering providers should serve a significant portion of

¹As described in the DSRIP Funding and Mechanics Protocol, it is important to note that this change only relates to MCO and ACH VBP incentives under DSRIP P4R and P4P. The VBP adoption targets remain for statewide accountability and are reinforced through the Apple Health Appendix and the state's managed care withhold program.

Medicaid covered lives in the region and represent a broad spectrum of care and related social services that are critical to improving how care is delivered and paid for.

- Engage and obtain formal commitment from partnering providers responsible for carrying out project activities.
- Develop a detailed implementation plan, including timing of activities, financial sustainability, workforce strategies, and population health management.
- Ongoing reporting of standardized process measures, including number of individuals served, number of staff recruited and trained, and impact measures as defined in the evaluation plan.

c. *Performance Metrics* (Statewide and Project-level Outcome Metrics)

See Appendix II for the project metrics that will be used to measure progress against meeting project goals and targeted levels of improvement against outcome-based performance indicators. Section III of the Funding and Mechanics Protocol provides further detail on how identified measures will be used to evaluate ACH performance.

d. *Value-based Payment Milestones*

Pursuant to STC 40, the state will update its Value-based Roadmap annually, which will address how the state will achieve its goal of converting 90 percent of Medicaid provider payments to reward outcomes by 2022. This Roadmap is a document that describes the payment reforms required for a high-quality and financially sustainable Medicaid delivery system and establishes VBP targets and incentives for the Managed Care Organizations (MCOs) and ACHs. This document also serves to revise and clarify the details surrounding Washington State's VBP incentives and framework.

Achievement of VBP targets will be assessed at both a regional and MCO-specific level. As indicated in Table 3, ACHs and MCOs will be rewarded based on reported progress in the early years of the demonstration. This will shift to rewarding for performance on the VBP targets.

Table 3. Value-based Payment Milestone Categories

Through this demonstration, the DSRIIP program and initiatives such as

the HealthCare Payment Learning Action Network will yield new best practices. Therefore, this Roadmap will be updated annually throughout the demonstration to ensure long-term sustainability of the improvements made possible by the DSRIP investment and that best practices and lessons learned can be incorporated into the state's overall vision of delivery system reform.

Washington will submit quarterly progress updates to CMS, which will include the progress made both in terms of total dollars included in VBP arrangements and quantitative and qualitative lessons learned.

V. Process for Project Plan Modification

No more than twice a year, ACHs may submit proposed modifications to an approved Project Plan for state review and approval/denial. In certain limited cases it may become evident that the methodology used to identify a performance goal and/or improvement target is no longer appropriate, or that unique circumstances/developments outside of an ACH's control require the ACH to modify its original plan. Examples of these circumstances could include a significant regulatory change that requires an ACH to cease a planned project intervention or initiate substantial changes to the way a standard performance metric is measured, requiring an ACH to modify its planned approach.

In order to request a Project Plan modification, an ACH must submit a formal request, with supporting documentation, for review by the state. The state will have 60 calendar days to review and respond to the request. Allowable Project Plan modifications are not anticipated to change the overall ACH project incentive valuation. However, modifications to decrease scope of a project may result in a decrease in the valuation of potential earnable funds. Unearned funds as a result of a decrease in the scope of a project will be directed to the Reinvestment pool and earned in accordance with the DSRIP Funding and Mechanics Protocol (Attachment D). The state will not permit modifications that lower expectations for performance because of greater than expected difficulty in meeting a milestone. Removal of a planned project intervention may result in a forfeiture of funding for that project as determined by the state,

VI. Health Information Technology. (The state will discuss how it plans to meet the Health IT goals/milestones outlined in the STCs.)

In accordance with STC 39, the state will use Health Information Technology (“Health IT”) and Health information exchange services to link core providers across the continuum of care to the greatest extent possible. To detail how the state will achieve its stated Health IT goals, the state will provide a Health IT strategy by April 1, 2017. That document provides detailed tactics and initiatives, technical gaps addressed, critical actions, policy levers and key metrics in place or planned for the following key business processes:

1. Addressing data needs and gaps
2. Acquiring Clinical Data
3. Leveraging Data Resources
4. Supporting clinical decisions with integrated patient information
5. Ensuring data integrity
6. Making large sets of clinical data available for program and business decisions