

**CATALYST IMPLEMENTATION BRIEF**

**Implementing an innovative contract**

The contract is signed—now what? Next, stakeholders must prepare to implement the innovative contract. This brief offers a checklist of potential considerations for executing the agreement, including aligning stakeholders and determining responsibilities, data access and analytics, ongoing management of the contract, and the potential roles for third parties.

These considerations may not apply to all contracts; the process will be determined by the organizations and products involved and the terms of the contract.

**What's covered**

- Internal stakeholder alignment
- External stakeholder alignment
- PA/medical coverage criteria
- Data access
- Data management and analytics
- Financial management
- Contract management
- Customer support
- Other third parties

**INTERNAL STAKEHOLDER ALIGNMENT**

Within stakeholder organizations, different roles will be involved with executing the contract. Some people will only need to be aware of the project, while others will have an active role in implementation.

- Consider potential roles and responsibilities of:
  - Legal and compliance
  - Finance and accounting
  - Case/care management
  - Pharmacovigilance/Data analytics
  - Communications
  - Pricing
  - Global and local medical teams
  - Others
- Set up timelines and meetings to align with the contract's obligations. Take into account the timing of interim assessments, if needed
- Ensure all roles are aware of the project plan, timeline, expectations, etc.
- Conduct training on innovative contracting if required

**EXTERNAL STAKEHOLDER ALIGNMENT**

Coordination between different organizations (including both the contracting organizations and others involved with delivering the treatment) is also key for successful implementation.

- Identify key points of contact within the contracting organizations
- Identify third parties that will be engaged in contract execution
- Determine how parties will work together; this might include:
  - Roles and responsibilities
  - Designating decision-makers in each organization
  - Designating project managers
- Identify legal documents that may be required (such as data privacy and business associate agreements)
- Agree on the project plan, timeline and expectations
- Identify and complete compliance and other training
- Coordinate with providers as needed
- Consider patient logistics, which may include:
  - Patients' role in data collection
  - Assistance that may be needed during the treatment process

## PA/MEDICAL COVERAGE CRITERIA

Stakeholders must be aligned on prior authorization (PA) or medical coverage criteria for the treatment. Coverage criteria are typically specified by the contract requirements.

- Both parties should agree that the coverage criteria align with the contract requirements prior to treatments
- Provide lead time to process required approvals
- Payers should communicate any changes to coverage criteria, as required
- If there are further updates over the contract period, these should be agreed upon by all parties

## DATA ACCESS

In order for innovative contracts to be executed, information must be gathered and shared as defined in the contract. Stakeholders must identify and put in place processes to capture, analyze, and share those data.

- Identify data elements. These could include:
  - Beneficiary eligibility source
  - Eligible claims codes
  - Provider electronic health record information
- Identify data source(s) for each data element: where/how to access the information
- Agree upon data file transfer format, timing, anonymization, validation, and transfer process
- Execute data use agreements. These agreements should include:
  - Attention to security/privacy of data
  - Data uses and other controls

## DATA MANAGEMENT AND ANALYTICS

Data management and analysis processes should align with the contract, ensuring that requirements for determining success or failure in an eligible patient are met.

- Align all parties on the process for analyzing the data:
  - Who will be responsible?
  - What constitutes success or failure?
  - What is the required timeline for analysis?
- Agree upon and document a methodology for the data analysis
- Determine a process for reporting results:
  - Who receives the reports?
  - What is the format?
  - How do recipients access the reports?
  - What is the required timeline for reporting?
- Consider publishing results as real-world evidence:
  - Are the findings of this innovative contract worthwhile for publication?
    - The results do not need to be positive or negative, but should be of sufficient interest to warrant publication
  - Does the data use agreement allow for publication?
  - Does the contract allow for publication?
  - Do the organizations have capacity to prepare a publication?
  - Who is responsible for authoring the publication and what approvals will be needed?
  - Where will the findings be published?
  - Is an additional analysis plan required?

## FINANCIAL MANAGEMENT

Innovative contracts may impact an organization's budget and financial reporting.

- Set up banking connections for payment
- Forecast potential budget and financial impacts
- Consider special accounting considerations
- Government price reporting:
  - Will the contract impact government price reporting?
  - What process considerations need to be taken into account to ensure compliance with government price reporting?

## CONTRACT MANAGEMENT

Contracts should include compliance requirements and procedures for resolving any disputes that may arise.

- Establish a process for ongoing contract compliance, and/or audit procedures:
  - Timing will generally be specified in the contract
  - Audit processes and procedures should be agreed upon
  - Include reporting of adverse events (AE)
- Identify a dispute resolution process:
  - What triggers a dispute?
  - What is the process for raising a dispute?
  - What is the timeline for resolution?
  - Who is responsible for facilitating a final decision?

## CUSTOMER SUPPORT

- Identify a process for managing inquiries from interested stakeholders, such as patients or other third parties

## OTHER THIRD PARTIES

- Consider aligning the innovative contract with other third-party contract requirements, such as reinsurance/stop loss

## RELATED

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- [Innovative contracting 101](#)
- [Key terms for payment innovation](#)
- [Is an innovative contract right for you?](#)
- [Designing an innovative contract](#)

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