

How Clinical Trial Data Can Impact Reimbursement

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Introduction

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The Reimbursement Value Proposition

Reimbursement is a constant challenge for all stakeholders in today's cost-conscious healthcare environment.

By empowering yourself with knowledge relative to the fundamentals of reimbursement and healthcare economics, you will become a valuable resource to your customers and their business, ultimately making a positive impact on your business and your company's bottom line. kh

Reimbursement Requires an Integrated Approach

Product Development Phases

Feasibility → Development → **IDE Study** → **Release**
***must have support from Senior Management team and Board**

Reimbursement must be incorporated into the:

Clinical Strategy
Regulatory Strategy
Marketing Strategy

All strategies need to be developed early!

Reimbursement should be a forethought...not an afterthought!

Plan Ahead and Be Prepared!



The FDA vs. CMS

□ FDA= Safety and Efficacy

- all patients
- formal process
- stringently monitored data



□ CMS= Reasonable and Necessary

- patients >65 years
- informal process-simple application
- no guidance documents or templates for data collection



Integrating the Two

Protocol	FDA	CMS/Payers
Indications	Product code	Coverage criteria
Study Design	Non-inferiority	Superiority
Inclusion/Exclusion	Example: No workers comp	Examples: include Diabetics Patient >65
Outcomes	Device function	Clinical relevance
QOL		Return to normal daily activities
Study Duration	6 months-1 year	2-5 years follow up
Pharmaceutical Use		Narcotics, anti-depressants, etc.
Collection of economic data	N/A	Payers only

Why Collect Data for CMS During a Trial?

- ❑ To determine and validate the “cost” of a procedure
- ❑ To show *substantial clinical improvement* over the current standard of care
- ❑ To prove reasonable and medically necessary
- ❑ **To ensure positive coverage**
- ❑ **To ensure adequate payment**

How Does CMS Impact Longevity?

- Both subsets of data will impact coverage and payment of a technology or procedure
- Positive coverage means payment
 - Proof of reasonable and necessary via scientifically sound clinical data is necessary
- Adequate payment means sales (sales is \$revenue\$)
 - Proof of cost through the collection of hospital economic data is necessary



Section 1:

The Economic Data Collection

Economic Data

- Provided to CMS only to secure payment
- Language to collect patient economic information is incorporated into the critical trial documents:
 - HIPAA authorization
 - research agreements (physician and hospital)
 - patient informed consent
 - IDE protocol
 - NOTE: both patient and hospital must consent

The UB-04 Form

- ❑ The bill a hospital submits to a payer for reimbursement
- ❑ All CMS required data is on the “UB-04” form
- ❑ Collected by sponsor regardless if device is provided free of charge during the trial
- ❑ Collection process is established in an SOP
- ❑ Economic database is most often managed internally; it is *separate* from the FDA database
- ❑ Economic data is not submitted to the FDA

The UB-04 Data

- Critical data to collect for CMS includes:
 - a patient identifier (to validate age if necessary)
 - patient study ID#
 - Economic data elements must have the ability to be linked back to the patient's other CRFs by the assigned study ID number
 - admit date
 - discharge date (determines ALOS)
 - ICD-9 procedure codes (if inpatient)
 - CPT® codes (if outpatient)
 - ICD-9 diagnosis codes (all settings of care)
 - total hospital charges



Sample Hospital UB-04 Form

The Economic Data Collection SOP

- Outlines the process for obtaining the economic information
 - from the responsible hospital party
 - to the sponsor designee
 - into the database
- Establishes the timeline for collection
- What is the monitor's role?
- Process incorporated into monitor training



SOP Example

The Economic Database

- ❑ Simple excel spreadsheet is acceptable
- ❑ Data input represents only that information identified in the critical documents
- ❑ Identifies that a patient was hospitalized and a UB is expected
- ❑ Reports run routinely (bi-monthly)
- ❑ Data queries generated according to timeline in SOP to determine UBs expected but not received




Economic Database Example

Post-Trial Use of the Data

- ❑ Procedure cost is determined
- ❑ Device price point can be established
- ❑ Supportive documentation required for additional payment is obtained
 - pass-through payment (outpatient)
 - new tech APC designation (outpatient)
 - inpatient add-on
- ❑ Procedure re-assigned to a different APC or MS-DRG to cover cost
- ❑ Creation of a new APC or MS-DRG to cover cost

The EOB

- ❑ Payer remittance statement
- ❑ Details what was paid and how much
- ❑ Sponsor may use payment information to present to board or investors
- ❑ Identifies challenging payers
- ❑ Challenges
 - difficult to collect
 - confidential information
 - hospitals do not willingly share information
- ❑ EOB data is not required by CMS



Section 2:

Data Validating
Substantial Clinical Improvement

Data Validating

Substantial Clinical Improvement

- Must show substantial clinical improvement over the current standard of care in order to secure additional payment from CMS
 - inpatient add-on
 - outpatient pass-through (device only)
 - new technology APC designation
- Necessary to impact positive coverage
- Secondary endpoints may be powered to show substantial clinical improvement

CMS Determination of Substantial Clinical Improvement

- Does the technology:
 - Represent a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
 - Offer the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. The diagnosis made by such a device must affect the management of the patient.

CMS Determination of Substantial Clinical Improvement (cont.)

- Significantly improve clinical outcomes for a patient population as compared to currently available treatments. For example does the device:
 - reduce mortality rates
 - reduce the rate of device-related complications
 - decrease the subsequent diagnostic or therapeutic interventions
 - decrease the number of future hospitalizations or physician visits
 - produce more rapid beneficial resolution of the disease process
 - decrease pain, bleeding, or other quantifiable symptoms
 - reduce recovery time
 - allow the patient to return to activities of daily living sooner

Key Points to Remember

- It is critical to understand the specific needs of the key stakeholders
 - CMS wants “substantial clinical improvement” and economic data
 - The FDA wants safety and efficacy

- It is advantageous to combine both needs into a well-designed study.

- Having FDA clearance/approval does not mean the device will be reimbursed.

- The clinical protocol is critical to both the reimbursement and regulatory success-integrate strategies early in the development phase.

- Every trial is a “reimbursement” trial.

- Without positive reimbursement (coverage and payment) there will be no sales, thus no revenue.

- Collecting the appropriate data during a clinical trial will have a **POSITIVE** impact on Reimbursement!

Questions and Discussion

Thank You

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