



Compliance and Culture: How Design and Approach Can Help Support Clinical Trial Billing

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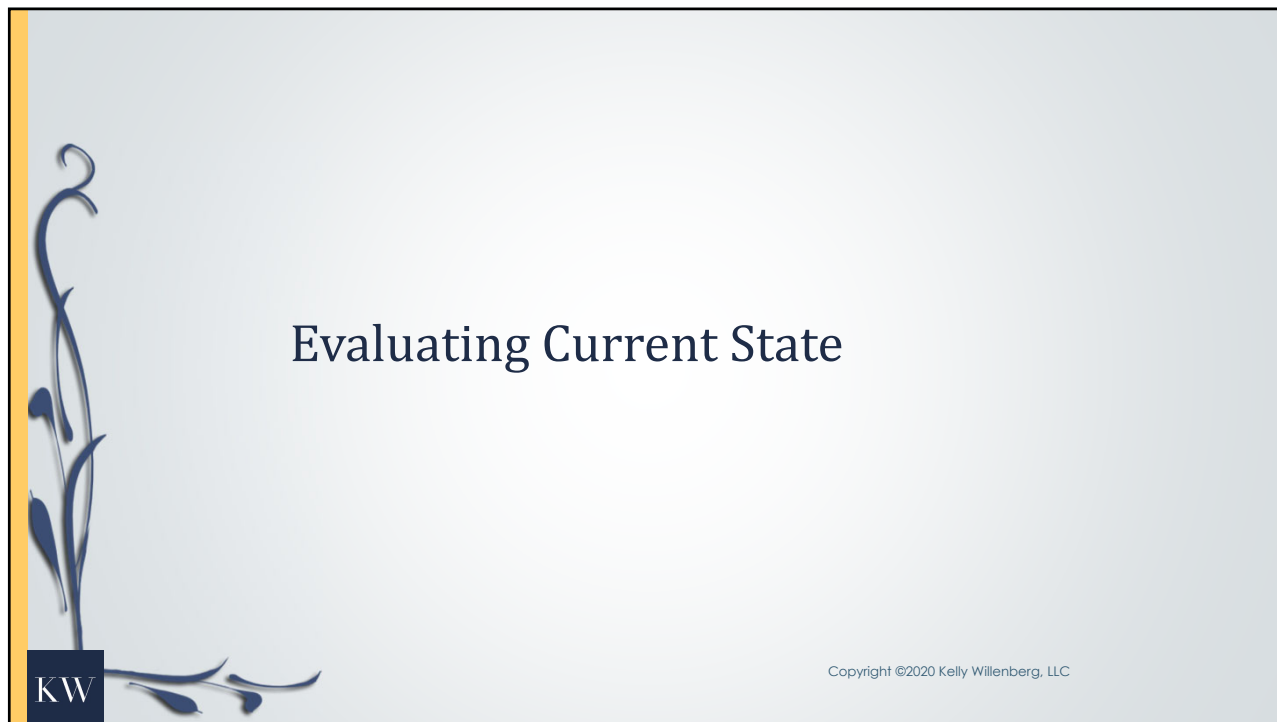
Essential Building Blocks for a Strong Billing Compliance Culture

- ▶ Defined roles with functional reporting relationships
- ▶ Outlined research finance business operations
- ▶ Training and verification of clinical research billing competency
- ▶ Tracked metrics with self monitoring and independent auditing

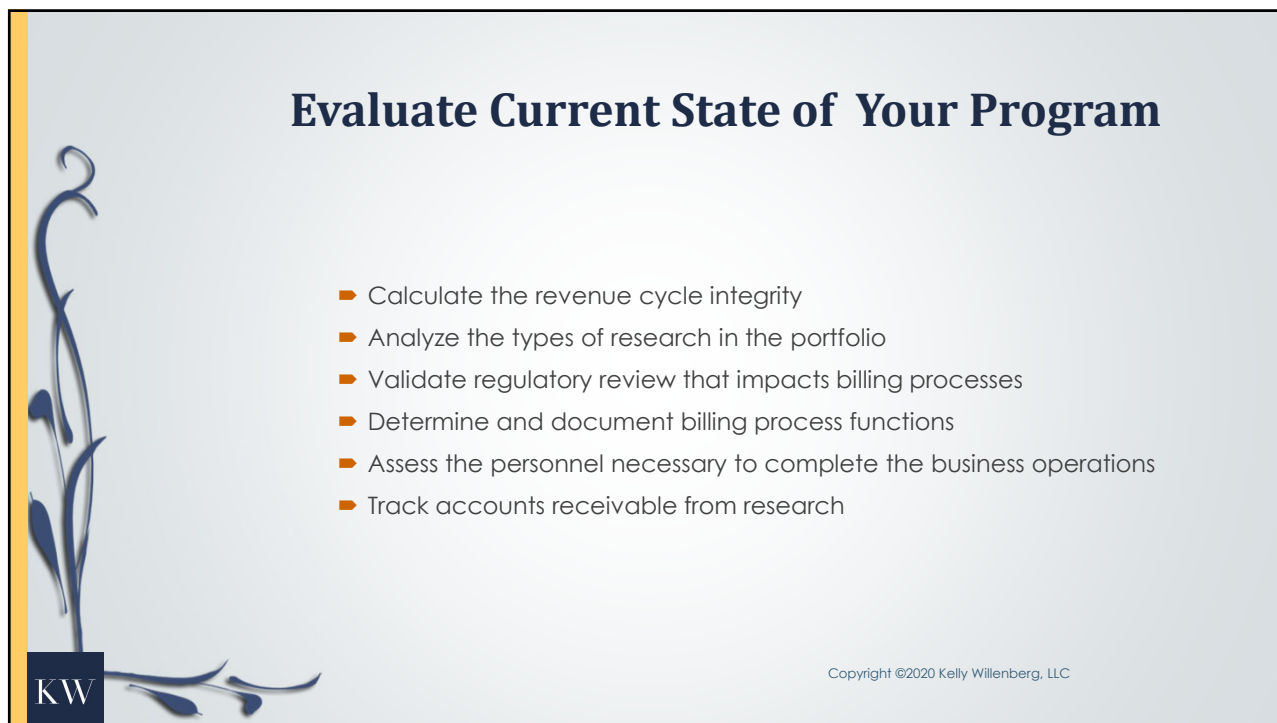
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Calculate Revenue Cycle Integrity

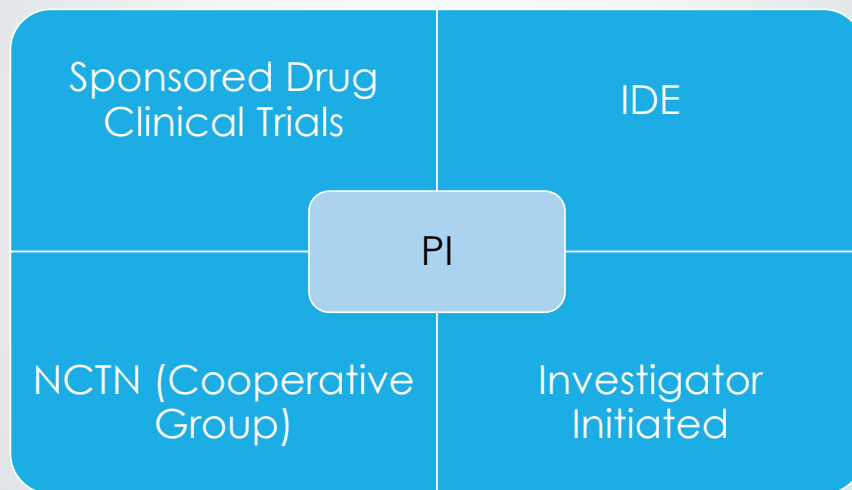
- ▶ Understand the business functions by evaluating revenue cycle
 - ▶ Coverage Analysis
 - ▶ Budgeting and Contracting
 - ▶ Charge Segregation
 - ▶ Invoicing to Sponsors
 - ▶ Reconciliation of Accounts Receivable
 - ▶ Payer Management Controls
 - ▶ Denial and Appeals Management
 - ▶ Write Offs

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Types of Research in the Portfolio



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Validate Regulatory Review That Impacts Billing Processes

- ▶ Cost language review in consents for discrepancies against contract, budget and coverage analysis
- ▶ Eliminate language that violates the Medicare Secondary Payer Rule
- ▶ Inspect Medicare Advantage language in ICF or contract for drug trials
- ▶ Appraise different IRBs and templated cost language

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Clinical Trial Billing Process

Coverage Analysis Review "Front End" Cycle

- ❖ Review protocol for feasibility
- ❖ Do a Qualifying Clinical Trial status
- ❖ Perform Coverage Analysis with validation
- ❖ Review draft budget, contract and consent
- ❖ National Guidelines for disease
- ❖ NCD's and LCD's applied

Document Review "Middle" Cycle

- ❖ Ensure Coverage Analysis guides all other documents
- ❖ Budget negotiation follows coverage analysis
- ❖ Contract language matches budget
- ❖ Consistency check confirming all documents prior to study opening

Patient On Study Review Back End

- ❖ Patient signs consent understanding financial implications
- ❖ Know every study and ever visit for each patient
- ❖ Segregate charges against Coverage Analysis and medical documentation
- ❖ Validate Coding rules and NCT# applied on claims
- ❖ Medicare Advantage review for drug clinical trials

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Assess The Personnel Necessary To Complete The Business Operations

- ▶ Examine the dynamics both with the upstream and downstream in regards to staffing resources and workload
- ▶ Inspect operational workflow with compliance in mind
- ▶ Construct an organizational structure with policies

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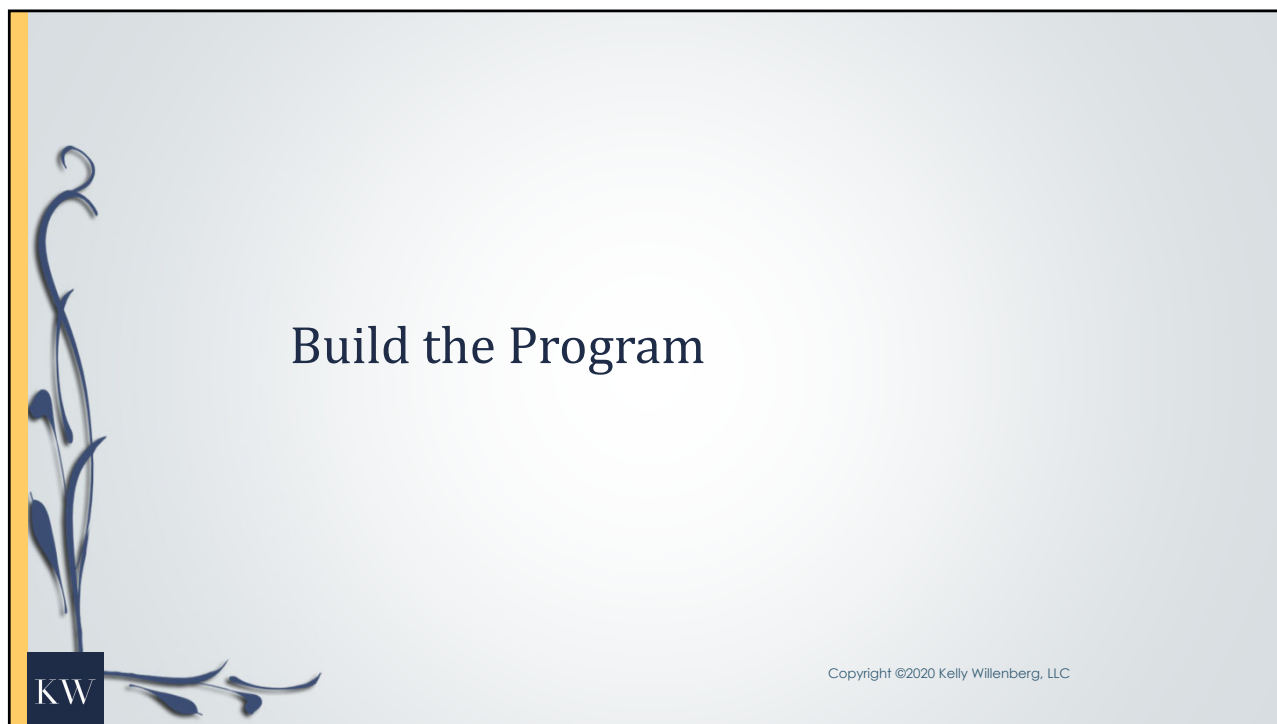
Track Accounts Receivable from Research

- ▶ Treat research as a business
- ▶ Cover your costs adequately by doing a thorough coverage analysis as the starting point for every study
- ▶ Evaluate studies upon closure and final payment received
- ▶ Manage and track losses to know the cost of doing business

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Build the Program

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Development of Job Function

- ▶ Create job description(s) for positions (billing analyst, coverage analyst, etc.)
- ▶ Current team member or new hire:
 - ▶ **Seeking:**
 - ▶ Hospital and physician billing background
 - ▶ Coding background
 - ▶ Revenue cycle analyst
 - ▶ Analytical
 - ▶ Sense of urgency

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Competency and Assessment

- Training Program
 - Conducting on-site training
 - Attending Conferences
 - Utilizing tools available via memberships/affiliations
- Building Competency
 - Yearly review of team member(s)
 - Develop checklist
 - Testing of competency
 - Observe, Review, Interact

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Establish Billing Compliance Program

- Policies and Procedures
 - Establish core set of polices
 - Billing Compliance
 - Responsibilities of reviews
 - Coverage analysis method
- Design billing compliance workflow
 - Develop with all stakeholders
- Implement communication plan
- Implement training program

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Leverage Technology

- ▶ What Exists at the Site?
 - ▶ Electronic Medical Record
 - ▶ Policies and Procedures
 - ▶ Functionality
 - ▶ Work Queues or Reports available
 - ▶ Clinical Trial Management System
 - ▶ Policies and Procedures
 - ▶ Functionality
 - ▶ Regulatory System
 - ▶ eRegulatory
 - ▶ Electronic server storage
 - ▶ Paper files

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Monitoring Plan

- ▶ Identify Billing Compliance Reviewer
 - ▶ Independent party to review
 - ▶ Preferred – Site Compliance Department
 - ▶ Billing compliance assessor
 - ▶ Quarterly Reviews – risk assessment
 - ▶ High enrolling studies
 - ▶ High volume investigators
 - ▶ New investigators
 - ▶ Review of first participant enrolled
 - ▶ Review entire workflow

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Metrics Assessment

- ▶ What's important to your site?
 - ▶ Volume reviewed
 - ▶ Number of studies in compliance or not
 - ▶ Dollar impact
 - ▶ Fee estimate for non-compliance
- ▶ Manager review
 - ▶ Follow up training site, individuals, etc.
 - ▶ System failure or workflow needs improvement
- ▶ **Document the review and work plan!**

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Elements for a Strong Program

- ▶ Clearly stated job description of role(s)
- ▶ Training program starts on hire date with a mentor assigned
- ▶ Open communication during development
- ▶ Buy-in of all stakeholders
 - ▶ Clinical, Finance, Departments, External Stakeholders (university, radiology, pharmacy, private practices), Compliance, Legal and C-Suite Executives
- ▶ Monitor plan and monthly reports
- ▶ Review, review and review

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Discussion and Questions?

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