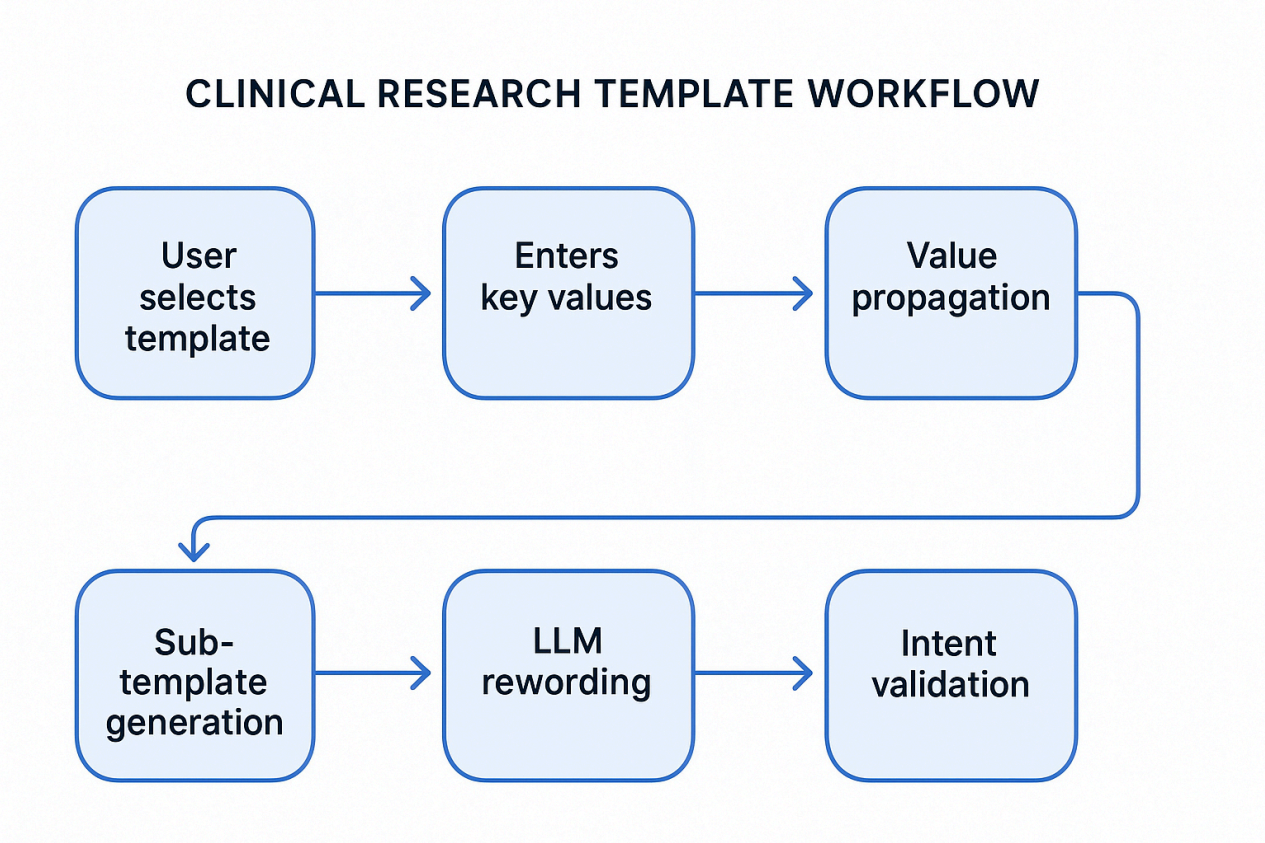
Clinical Research Study Protocol Sample Text Generation Workflow



Workflow Steps & Technical Specification

Step 1 User Selects Template (New IND/IDE)

- **Implementation**: Template catalog with metadata, UI selection interface
- **Example**: User chooses "IND/IDE" from dropdown menu
- **Data Flow**: Template ID → Template metadata + base structure

Step 2: User Enters Key Information Values

- **Implementation**: Dynamic form generation, validation rules, auto-complete
- **Example**: "Heart XYZ Device", cardiovascular indication, Phase II study
- **Data Flow**: User inputs → Structured data object (StudyParameters)

Step 3: Sub-template Selection/Generation

- **Implementation**: Rule-based template selection, conditional section inclusion
- **Example**: Device-specific sections vs drug sections selected automatically
- **Data Flow**: StudyParameters + Template rules → Selected sub-templates

Step 4: Value Propagation Through Text

- **Implementation**: Handlebars/Liquid template engine, variable substitution
- **Example**: "Heart XYZ Device" propagates to all device references throughout document
- **Data Flow**: Sub-templates + StudyParameters → Raw generated text

Step 5: LLM Rewording for Readability

- **Implementation**: Structured prompts, section-by-section processing, style guide enforcement
- **Example**: Improve flow and clinical terminology while preserving technical details
- **Data Flow**: Raw text → LLM API → Improved text with metadata

Step 6: LLM Intent Validation

- **Implementation**: Fact extraction, key information preservation check, change impact assessment
- **Example**: Ensure "Heart XYZ Device" specifications remain unchanged after rewording
- **Data Flow**: Original + Reworded text → Validation report + Approved text

Step 7: Human Review

- **Implementation**: Side-by-side comparison interface, change tracking, approval workflow
- **Example**: Clinical expert reviews and approves final document
- **Data Flow**: Final text + validation → Human feedback → Approved document

Key Implementation Code Structure

```
public class ClinicalTemplateProcessor
{
    // Step 1: Template Selection
    public Template SelectTemplate(string templateType) { }
```

```
    // Step 2: Collect Key Information
    public StudyParameters CollectUserInput() { }

    // Step 3: Sub-template Selection
    public List<SubTemplate> SelectSubTemplates(Template template, StudyParameters parame

    // Step 4: Value Propagation
    public string GenerateRawText(List<SubTemplate> subTemplates, StudyParameters paramet

    // Step 5: LLM Rewording
    public async Task<string> ImproveReadability(string rawText, StudyParameters paramete

    // Step 6: Intent Validation
    public ValidationResult ValidateIntent(string original, string rewritten, StudyParame

    // Step 7: Human Review Interface
    public ReviewDocument PrepareForHumanReview(string finalText, ValidationResult valida
}
```

Critical Design Considerations

Template Structure: Your IND/IDE templates would be broken into sub-templates based on:

- **Regulatory section** (device vs drug vs biologic)
- **Therapeutic area** (cardiovascular vs oncology vs neurological)
- **Study phase** (early vs pivotal vs post-market)

Validation Strategy: Steps 6-7 are crucial for clinical compliance - the LLM validation ensures that critical information like device specifications, dosing, or safety parameters aren't accidentally modified during the rewording process.

Human-in-the-Loop: Step 7 maintains regulatory compliance by requiring clinical expert review, while Steps 5-6 provide AI assistance to improve quality and catch potential issues before human review.

This workflow balances **efficiency** (automated template generation) with **safety** (validation and human oversight) - essential for clinical research where accuracy and compliance are paramount.