

**Clinical Research Trial Feasibility Training: Content & Flow Structure**  
**Clinical Research Pro**

## **Training Flow Architecture**

### **Entry Assessment & Personalization**

**Duration:** 5-10 minutes

#### **Role-Based Entry Point**

1. **"What's your primary role?"**
  - Clinical Research Associate
  - Project/Study Manager
  - Medical Affairs
  - Business Development
  - Site Personnel
  - Regulatory Affairs

2. **Experience Level Assessment**

- Novice (0-2 years)
- Intermediate (2-5 years)
- Advanced (5+ years)
- Expert (10+ years)

3. **Learning Objective Selection**

- "I need to understand feasibility basics"
- "I want to improve my assessment skills"
- "I need to make better go/no-go decisions"
- "I want to optimize existing processes"

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## **Module 1: Feasibility Foundations**

## **1 Why Feasibility Matters**

### **Universal Opening (All Learners - 15 minutes)**

#### **Hook: The \$2.6 Billion Question**

- **Interactive Statistic:** "Average cost to bring a drug to market"
- **Reveal:** "68% of trials fail to meet enrollment targets"
- **Question:** "What if we could predict and prevent these failures?"

#### **Case Study Carousel: "Famous Feasibility Failures"**

##### **1. The Alzheimer's Mega-Trial**

- 18-month delay due to site readiness issues
- \$200M budget overrun
- Learner choice: "What went wrong?"

##### **2. The Rare Disease Rush**

- Overestimated patient population by 300%
- 3 competing trials launched simultaneously
- Learner choice: "How could this be prevented?"

##### **3. The Perfect Protocol Problem**

- Inclusion criteria too restrictive
- Only 12% of screened patients eligible
- Learner choice: "What would you change?"

#### **Branching Point 1: Learning Depth**

##### **Path A: Feasibility Fundamentals (Novice)**

###### **Content Flow:**

###### **1. 3 What is Feasibility? - Interactive Definition Builder**

- Drag key concepts to build comprehensive definition
- Real-time feedback on completeness

###### **2. "The Feasibility Ecosystem" - Stakeholder Map**

# Summary of Comments on Microsoft Word - Document1

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## Page: 2

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<input type="checkbox"/>	Number: 1	Author: Nick Palumbo	Subject: Comment on Text	Date: 11/2/2025 6:02:29 PM
This will differ depending on whether the person is from a site, CRO or sponsor				
<input type="checkbox"/>	Number: 2	Author: Nick Palumbo	Subject: Comment on Text	Date: 11/2/2025 6:07:33 PM
What contributes to this failure?				
<ul style="list-style-type: none"><li>- sponsor or CRO selecting the wrong sites</li><li>- site's lack of understanding of the protocol or patient journey</li><li>- site's over confidence in ability to enroll</li><li>- competing studies</li><li>- ability of the site to effectively recruit and consent patients</li><li>- limited site resources or site has too many studies to effectively manage</li></ul>				
<input type="checkbox"/>	Number: 3	Author: Nick Palumbo	Subject: Comment on Text	Date: 11/2/2025 6:08:33 PM
I recommend this be part of training for all experience levels.				

- Click through different stakeholder perspectives
- Understand impact on each group

### 3. "Cost of Poor Feasibility" - Impact Calculator

- Adjust variables to see cost implications
-  Timeline delays, budget overruns, opportunity costs

## Path B: Strategic Feasibility (Intermediate/Advanced)

### Content Flow:

1.  "Feasibility Frameworks Comparison"
  - Side-by-side analysis of industry approaches
  - Interactive framework selector tool
2.  "Protocol of Good Feasibility"
  - Business case development
  - Quantitative impact modeling

### Convergence Activity: Protocol Synopsis Deep Dive

All learners reconvene for hands-on practice

### Interactive Exercise: "Red Flag Radar"

- **Scenario:** Review actual protocol synopsis (anonymized)
- **Task:** Identify potential feasibility issues
- **Tools:**
  - Highlighting tool for concerning text
  - Risk categorization dropdown
  - Impact assessment slider (1-10)

### Immediate Feedback Loop:

- **Green flags:** "Good catch! This could impact..."
- **Missed issues:** "Consider this aspect..."
- **Bonus points:** For identifying subtle issues

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Number: 1

Author: Nick Palumbo

Subject: Sticky Note Date: 11/2/2025 6:10:12 PM

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5 Author: Nick Palumbo Subject: Sticky Note Date: 11/2/2025 6:14:56 PM

Poor feasibility can cause these issues. However, poor feasibility also can cause a study to enroll significantly faster than projected, if the projections are too conservative. This has additional down stream impacts such as clinical supply and drug supply issues, data monitoring issues, etc.

A good feasibility assessment is one that results in predictable delivery of a study within an acceptable window of the projected study timeline.

Number: 2

Author: Nick Palumbo

Subject: Sticky Note Date: 11/2/2025 6:17:33 PM

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This can vary based on the sponsor. Biotechs and small pharma will have different perspectives and approaches compared to large pharma or commercial stage companies.

Number: 3

Author: Nick Palumbo

Subject: Sticky Note Date: 11/2/2025 6:18:01 PM

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I'm interested in this definition.

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## Module 2: Patient Population & Recruitment Feasibility

"Finding Your Patients"  [1]

### Opening Hook: "The Needle in the Haystack Challenge"

- **Interactive Map:** Global disease prevalence visualization
- **Reality Check:** "Your target: 500 patients with [rare condition]"
- **Question:** "Where do you start?"

### Core Content Sequence (20-25 minutes)

#### 2.1 Epidemiological Analysis

##### Learning Flow:

1. **"Disease Landscape Mapping"**
  - Interactive prevalence calculator
  - Geographic distribution analysis
  - Demographic breakdowns
2. **"The Inclusion/Exclusion Impact"**
  - **Exercise:** Modify criteria and see patient pool changes
  - **Real-time calculator:** Shows percentage reduction per criterion
  - **Visual funnel:** Patient eligibility flow
3. **"Competitive Intelligence"**
  - **Database simulation:** Search competing trials
  - **Impact assessment:** Patient pool overlap analysis

##### Branching Scenario: "The Recruitment Dilemma"

**Setup:** Oncology trial needs 300 patients,  [2] stage II-III breast cancer, specific biomarker

**Branch Decision Point:** "Your biggest concern is..."

**Branch A: Geographic Reach**

**Content Focus:** Site distribution and patient access

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Number: 1 Author: Nick Palumbo Subject: Sticky Note Date: 11/2/2025 6:26:03 PM

Don't forget about trial equity and creating a strategy to recruit a diverse patient population.

Regardless of changes to DEI initiatives, it remains imperative for nearly all sponsors that the study enrolls a representative population.

Number: 2 Author: Nick Palumbo Subject: Sticky Note Date: 11/2/2025 6:37:16 PM

What about line of treatment?

- **Interactive Map Tool:** Plot potential sites
- **Travel burden analysis:** Patient catchment areas
- **Cultural considerations:** Regional differences in trial participation

**Scenario Evolution:** Rural vs. urban site selection challenges  1

- **Decision:** Fewer urban sites vs. more rural sites
- **Consequences:** Different recruitment timelines and costs

### Branch B: Eligibility Criteria

**Content Focus:** Inclusion/exclusion optimization

- **Criteria Impact Simulator:** Adjust requirements, see patient pool changes
- **Medical necessity vs. feasibility:** Balance scientific rigor with recruitment reality
- **Regulatory considerations:** What can/cannot be modified

**Scenario Evolution:** Sponsor pushes back on criteria relaxation

- **Decision:** Stand firm vs. compromise vs. alternative solutions
- **Consequences:** Different risk profiles and timelines

### Branch C: Patient Engagement Strategy

**Content Focus:** Recruitment and retention approaches  2

- **Patient journey mapping:** Identify engagement touchpoints
- **Digital recruitment tools:** Social media, patient registries, telemedicine
- **Retention strategies:** Reducing dropout rates

**Scenario Evolution:** Low enrollment after 6 months  3

- **Decision:** Pivot strategy vs. add sites vs. extend timeline
- **Consequences:** Budget and timeline implications

### Convergence Exercise: "Recruitment Reality Check"

All branches reconvene for integrated assessment

### Multi-Variable Optimization Challenge

- **Given:** Fixed budget, timeline, and quality requirements

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Number: 1 Author: Nick Palumbo Subject: Sticky Note Date: 11/2/2025 6:39:13 PM  
Community sites vs. large medical centers

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Number: 2 Author: Nick Palumbo Subject: Sticky Note Date: 11/2/2025 6:58:37 PM  
How do you address placebo-controlled studies?

How do you account for the impact to enrollment when there is an approved treatment (Standard of Care)?

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Number: 3 Author: Nick Palumbo Subject: Sticky Note Date: 11/2/2025 6:41:36 PM  
Monitor enrollment trends and leading indicators: site activations and screened patients.  
Site/PI assessment of enrollment challenges

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- **Task:** Balance geographic reach  eligibility criteria, and engagement strategy
- **Tool:** Interactive slider interface with real-time feasibility scoring

### Peer Learning Component

- **Share solutions:** Compare approaches across learners
  - **Vote on best strategy:** Crowd-sourced validation
  - **Expert commentary:** AI-generated insights on popular choices
- 

## Module 3: Site Selection & Capability Assessment

*"Building Your Site Network"*

### Opening: "The Site Selection Paradox"

- **Dilemma presentation:** "Perfect sites don't exist"
- **Interactive trade-off:** Patient volume vs. experience vs. geography vs. cost
- **Question:** "What matters most for YOUR trial?"

### Personalized Learning Path Selection

#### Path Selection Based on Trial Type:

Learner chooses their scenario:

- **A:** Large Phase III cardiovascular outcomes trial
- **B:** Small Phase I oncology dose-escalation study 
- **C:** Medical device feasibility study
- **D:** Pediatric rare disease trial

#### Core Content Framework (Adapted by Path)

##### 3.1 Site Capability Assessment

###### For Path A (Large Phase III):

**Content Focus:** Scale and standardization

- **Site network mapping:** Geographic coverage optimization
- **Standardization requirements:** Protocol compliance across sites

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- Number: 1 Author: Nick Palumbo Subject: Sticky Note Date: 11/2/2025 6:45:37 PM  
Country specific and/or regional enrollment targets are important to ensure data is accepted by regulatory authorities for drug approval.  
Some countries require a specific percentage of patients enrolled in order for the sponsor to be able negotiate drug costs, otherwise the country dictates the price the sponsor can charge.
- Number: 2 Author: Nick Palumbo Subject: Sticky Note Date: 11/2/2025 6:50:12 PM  
Most are using a BON design.  
Need to account for rules for escalation and deescalation.  
When patients can be screened for the next cohort

- **Volume projections:** Patient flow analysis per site

**Interactive Tool:** "Network Builder"

- **Map interface:** Select sites across regions
- **Capability scoring:** Automated assessment based on criteria
- **Risk analysis:** Network-level vulnerability assessment

**For Path B (Phase I Oncology):**

**Content Focus:** Specialized expertise and safety

- **Investigator qualifications:** Oncology experience requirements
- **Safety infrastructure:** 24/7 monitoring capabilities
- **Regulatory compliance:** Phase I specific requirements

**Interactive Tool:** "Expert Matcher"

- **Investigator database:** Search by specialty and experience
- **Facility assessment:** Safety equipment and procedures checklist
- **Risk evaluation:** Patient safety protocol verification

## 3.2 Site Evaluation Deep Dive 1

**Universal Content Structure:**

1. **"The Site Visit Simulator"**
  - **Virtual facility tour:** 360° interactive environment
  - **Checklist completion:** Click through assessment criteria
  - **Red flag identification:** Spot potential issues
2. **"Staff Capability Matrix"**
  - **Role mapping:** Match staff to protocol requirements
  - **Training needs assessment:** Identify gaps and solutions
  - **Backup planning:** Contingency for staff turnover

**Branching Decision Point:** "The Imperfect Site Dilemma"

**Scenario Setup:** Three potential sites, each with trade-offs

Number: 1

Author: Nick Palumbo

Subject: Sticky Note Date: 11/2/2025 6:52:54 PM

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How about best practices for developing feasibility questionnaires?

### **Site A: High Volume, Low Experience**

- **Pros:** 50+ eligible patients/month, enthusiastic team
- **Cons:** Limited research experience, basic infrastructure
- **Learning Path:** Site development and training strategies

#### **Content Flow:**

- **Training program design:** Protocol-specific education plans
- **Infrastructure development:** Equipment and system upgrades
- **Risk mitigation:** Enhanced monitoring strategies

### **Site B: Expert Team, Low Volume**

- **Pros:** Renowned investigator, excellent research infrastructure
- **Cons:** Only 5-8 eligible patients/month, high costs
- **Learning Path:** Optimization and network strategies

#### **Content Flow:**

- **Patient referral networks:** Building catchment area
- **Cost-benefit analysis:** Premium site value assessment
- **Timeline implications:** Quality vs. speed trade-offs

### **Site C: Balanced but Constrained**

- **Pros:** Moderate volume and experience, reasonable costs
- **Cons:** Limited availability, competing trial commitments
- **Learning Path:** Negotiation and relationship management

#### **Content Flow:**

- **Contract negotiation:** Securing commitment and priority
- **Relationship building:** Long-term partnership strategies
- **Contingency planning:** Backup options and flexibility

### **Advanced Integration Exercise: "Site Network Optimization"**

#### **Multi-Criteria Decision Analysis**

- **Weighted scoring system:** Learner sets priorities
- **Sensitivity analysis:** See how weight changes affect rankings
- **Portfolio approach:** Optimize entire network, not individual sites

### **Collaborative Challenge: "The Site Selection Committee"**

- **Role-based perspectives:** Medical, operational, financial viewpoints
  - **Consensus building:** Navigate conflicting priorities
  - **Final recommendation:** Justify selection to virtual leadership team
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## **Module 4: Regulatory & Compliance Feasibility**

*"Navigating the Regulatory Maze"*

### **Opening: "The Regulatory Reality Check"**

- **Timeline visualization:** Regulatory milestones on critical path
- **Interactive question:** "What's the longest regulatory delay you've experienced?"
- **Reality reveal:** Average regulatory timelines by region and indication

### **Geographic/Regulatory Branching**

#### **Initial Path Selection:**

*"Where will your trial run?"*

- **US Only:** FDA-focused pathway
- **EU Only:** EMA-focused pathway
- **Multi-Regional:** Global regulatory strategy
- **Emerging Markets:** BRICS+ considerations

### **Content Flow by Regulatory Path**

#### **Path A: FDA-Focused (US Trials)**

##### **4.1 FDA Landscape Navigation**

#### **Content Sequence:**

1. **"IND Strategy Selection"**

- **Decision tree:** IND vs. IDE vs. exemptions
  - **Interactive flowchart:** Answer questions to determine pathway
  - **Timeline implications:** Each pathway's impact on study start
2. "FDA Communication Strategy"
- **Pre-IND meetings:** When and how to engage
  - **Type B vs. Type C meetings:** Strategic selection
  - **Question formulation:** Interactive exercise in crafting effective questions

## 4.2 Regulatory Timeline Builder

### Interactive Tool Features:

- **Drag-and-drop milestones:** IND submission, FDA response, amendments
- **Dependency mapping:** Show critical path relationships
- **Risk scenario planning:** "What if FDA requests more information?"

## Path B: EMA-Focused (EU Trials)

### 4.1 EMA Regulatory Framework

#### Content Sequence:

1. "Clinical Trial Regulation (CTR) Navigation"
  - **Single submission process:** EU portal walkthrough
  - **Member state considerations:** National requirements overlay
  - **Timeline expectations:** Realistic approval timelines
2. "Scientific Advice Strategy"
  - **When to seek advice:** Decision framework
  - **Question prioritization:** Most valuable advice topics
  - **Multi-stakeholder meetings:** Coordinating with HTA bodies

## Path C: Multi-Regional Strategy

### 4.1 Global Regulatory Complexity

#### Content Sequence:

## **1. "Regulatory Harmonization Assessment"**

- **ICH guidelines application:** Regional interpretation differences
- **Submission timing strategy:** Sequential vs. parallel approaches
- **Resource allocation:** Regulatory affairs team distribution

## **2. "Cultural and Regional Considerations"**

- **Local regulatory culture:** Communication styles and expectations
- **Ethical considerations:** Regional IRB/EC differences
- **Language and translation:** Documentation requirements

**Convergence Scenario: "The Regulatory Crisis"**

**All paths reconvene for crisis management simulation**

**Crisis Scenario Setup:**

**"Six months into your trial, you receive unexpected regulatory feedback that could impact your global program..."**

**The Crisis:** FDA raises safety concerns that weren't anticipated by EMA

- **Immediate decisions needed:** Continue enrollment? Pause globally? Regional approach?
- **Stakeholder management:** Investigators, sponsors, patients, other regulators
- **Communication strategy:** What to say, when, and to whom?

**Branching Crisis Response:**

**Response A: Global Pause**

**Learning Content:**

- **Crisis communication templates:** Stakeholder-specific messaging
- **Regulatory coordination:** Managing multiple agency relationships
- **Restart strategies:** Requirements for resuming enrollment

**Response B: Regional Approach**

**Learning Content:**

- **Risk-benefit assessment:** Regional vs. global decision making

- **Data integrity considerations:** Managing different regional datasets
- **Regulatory relationship management:** Maintaining trust across agencies

### **Response C: Continue with Enhanced Monitoring**

#### **Learning Content:**

- **Enhanced safety monitoring:** Additional requirements and costs
- **Informed consent updates:** Patient communication strategies
- **Data monitoring committee:** Enhanced oversight implementation

#### **Advanced Exercise: "Regulatory Strategy Optimization"**

#### **Multi-Variable Regulatory Planning**

#### **Interactive simulation includes:**

- **Timeline optimization:** Balance speed vs. thoroughness
  - **Resource allocation:** Regulatory affairs team deployment
  - **Risk assessment:** Probability and impact of regulatory delays
  - **Contingency planning:** Alternative pathways and backup strategies
- 

### **Module 5: Budget & Resource Feasibility**

#### *"The Financial Reality"*

#### **Opening: "The Budget Balancing Act"**

- **Interactive cost reveal:** "Guess the cost of..." various trial components
- **Reality check:** Actual industry benchmarks
- **Personal reflection:** "What's your biggest budget surprise?"

#### **Role-Based Content Branching**

#### **Branch Selection: "What's your budget responsibility?"**

- **A:** Overall trial budget ownership
- **B:** Site budget and payments
- **C:** Vendor and CRO management

- **D:** Resource allocation and optimization

## **Core Financial Feasibility Framework**

### **5.1 Budget Architecture Understanding**

#### **For Branch A (Overall Budget Ownership):**

##### **Content Flow:**

1. **"Budget Component Breakdown"**
  - **Interactive pie chart:** Click through major cost categories
  - **Benchmarking tool:** Compare to industry standards
  - **Sensitivity analysis:** Impact of key variable changes
2. **"Cost Driver Identification"**
  - **Pareto analysis:** 80/20 rule in trial costs
  - **Variable vs. fixed costs:** Understanding cost behavior
  - **Hidden cost identification:** Often overlooked expenses

#### **For Branch B (Site Budget Focus):**

##### **Content Flow:**

1. **"Site Payment Strategy"**
  - **Payment model comparison:** Per patient vs. milestone vs. hybrid
  - **Competitive analysis:** Market rates by geography and indication
  - **Performance incentives:** Designing effective bonus structures
2. **"Site Cost Optimization"**
  - **Efficiency improvements:** Reducing site burden
  - **Technology solutions:** Cost-effective site support tools
  - **Negotiation strategies:** Win-win site agreements

### **5.2 Interactive Budget Builder**

#### **Universal Tool (Adapted by Branch):**

- **Component-based calculator:** Build budget from ground up

- **Real-time feasibility scoring:** Budget reasonableness assessment
- **Scenario modeling:** "What if" analysis capabilities
- **Benchmark comparison:** Industry standard ranges

### **Major Branching Scenario: "The Budget Crisis"**

#### **Crisis Setup:**

**"Three months before study start, you're told the budget must be cut by 30%. The timeline cannot change, and scientific integrity must be maintained."**

#### **Crisis Response Paths:**

##### **Path A: Site Network Reduction**

###### **Learning Content:**

- **Site prioritization matrix:** Ranking sites by value contribution
- **Geographic coverage impact:** Maintaining representative population
- **Timeline risk assessment:** Fewer sites = longer enrollment?

###### **Interactive Exercise:**

- **Site elimination simulator:** Remove sites and see impact
- **Risk mitigation strategies:** Compensating for reduced network
- **Stakeholder communication:** Managing site disappointment

##### **Path B: Protocol Simplification**

###### **Learning Content:**

- **Endpoint prioritization:** Primary vs. secondary vs. exploratory
- **Visit optimization:** Reducing frequency without compromising safety
- **Procedure elimination:** Non-essential assessments identification

###### **Interactive Exercise:**

- **Protocol streamlining tool:** Remove components and see savings
- **Scientific impact assessment:** Maintaining study validity
- **Regulatory implications:** What changes need approval?

## **Path C: Timeline Extension**

### **Learning Content:**

- **Cost-time trade-offs:** Longer studies, different cost structure
- **Opportunity cost analysis:** Delayed market entry implications
- **Resource reallocation:** Spreading costs over longer period

### **Interactive Exercise:**

- **Timeline optimization:** Balance cost reduction with delay impact
- **Cash flow modeling:** Payment timing adjustments
- **Competitive intelligence:** Market window considerations

### **Advanced Integration: "ROI Optimization Challenge"**

### **Multi-Objective Optimization**

#### **Learners must balance:**

- **Cost minimization:** Stay within budget constraints
- **Timeline optimization:** Minimize delays
- **Quality maintenance:** Preserve scientific integrity
- **Risk management:** Acceptable risk levels

#### **Interactive Dashboard:**

- **Real-time scoring:** Overall feasibility assessment
- **Trade-off visualization:** See impact of each decision
- **Sensitivity analysis:** Test robustness of solution
- **Peer comparison:** How do others solve the same challenge?

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### **Assessment & Knowledge Integration Points**

#### **Continuous Assessment Strategy**

#### **Micro-Assessments (Throughout Each Module)**

- **Decision quality scoring:** Points for optimal choices

- **Knowledge checks:** 2-3 questions per major concept
- **Application exercises:** Immediate practice opportunities

### **Module Integration Points**

- **Cross-module scenarios:** Combine learnings from multiple areas
- **Cumulative case building:** Add complexity as knowledge grows
- **Peer collaboration:** Share insights and learn from others

### **Adaptive Content Delivery**

#### **Performance-Based Branching**

- **Struggling learners:** Additional support content and simpler scenarios
- **Advanced learners:** Complex challenges and leadership scenarios
- **Mixed performance:** Targeted reinforcement in weak areas

#### **Interest-Based Customization**

- **Deep-dive options:** Extra content for engaged learners
- **Skip options:** Bypass familiar content for experienced users
- **Related content suggestions:** "If you liked this, try..."