

# About Me



## Amy Mou – Vendor Strategy Management Expert

- Professional Journey Summary
- Background:
  - Finance and Finance Technology Sector: 6 years of experience.
  - Spent a year raising my kid while being an educator
  - 6 years of R&D Vendor Outsourcing Management experience.
  - Graduated from NCSU with a background in applied mathematics and statistics.
- Career Transition:
  - Moved to Oncology Vendor Management.
- Early Passion in Biotechnology:
  - Undergraduate research on epithelial cell growth using Newton's three laws and Hooke's law.
- Notable Experience:
  - Worked at Exelixis: Financial Operations Team.
  - Currently work as an FSP on assignment with a large pharmaceutical company.
- Certifications:
  - Contract Management Certification from UCLA extension December 2022.
  - Foundations of Clinical Research from PCC expected completion March 2025.



# Disclaimer

THE INFORMATION PROVIDED IN THIS PRESENTATION REPRESENTS MY PERSONAL VIEWS, IDEAS, AND OPINIONS. IT IS NOT INTENDED TO REFLECT OR REPRESENT THE VIEWS, POSITIONS, OR POLICIES OF MY CURRENT OR PAST EMPLOYERS.



# Strategic Close-Out Process Begins with a finish in mind

## CRITICAL STEPS FOR SUCCESSFUL CONTRACT CLOSE-OUT

Amy Mou  
Vendor Strategy Expert in R&D Oncology  
Currently an FSP on assignment with a large  
pharmaceutical company

Let's check your knowledge about contract close-out!



# Close out key words and key emotions involved





# Start by Thinking about How It Will End

## Understanding End Date and Termination Clauses

Recognizing the purpose of termination clauses is vital for effective contract management and compliance.

## Legal Implications

It's important to consider the legal implications of terminating a contract, ensuring all actions comply with regulations.

## Effective Communication

Clear communication regarding termination is essential. All parties must understand the implications and next steps involved including a verbal or email notification of the termination of contract and what needs to be done prior to service closeout.



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A contract serves as a safety net and the termination clause prepares for worst-case scenarios or the orderly conclusion of services.

- Key scenarios include:
- **Study completion or early termination** (e.g., safety concerns, endpoint achievement)
- **Company mergers, acquisitions, or sponsor transitions**
- **Regulatory or compliance changes** (e.g., FDA, EMA requirements)
- **Budget constraints or funding withdrawals**
- **Vendor performance issues** (e.g., missed milestones, data quality concerns)
- **Force majeure events** (e.g., pandemics, geopolitical disruptions)
- **Pipeline reprioritization or therapeutic focus shifts**



# Risks of Lacking a Defined Close-Out Process and Termination Clause



Increased financial discrepancies can arise without proper reconciliation.



Potential for legal disputes due to unaddressed contract obligations.



Loss of critical documentation may hinder future audits and reviews.



Missed opportunities for learning from closed projects can impact future success.



Reputational damage may occur if stakeholders perceive mismanagement.



# Termination Clause is typically included in the Master Service Agreement

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# Key Points of Master Service Agreements



- Define the scope of services clearly to avoid misunderstandings.
- Establish clear terms for payment and invoicing procedures.
- Include confidentiality clauses to protect sensitive information.
- Outline dispute resolution mechanisms to manage conflicts effectively.
- **Set termination conditions to allow for flexible contract management.**
- Include insurance limit and subcontractors if the information is available

## Contract Checklist



Ensure the end date is clearly stated in the contract.



Verify the presence of a termination clause for flexibility.





# Termination Clauses Overview

- **Termination for Convenience** allows no-cause termination with notice.
- **Termination for Cause** addresses breaches and insolvency issues.
- **Mutual vs Unilateral Termination** requires agreement between parties or one side to end.
- **Force Majeure** allows termination due to uncontrollable events.
- **Change in Control** provides notice for ownership changes.

# Key Considerations for Contract Closeout from the start

## Part 1



### Identify Exp. Date

Identify contract expiration date.



### Identify User Assess

Identify and access all necessary file repositories for efficient closure.



### Understand PII Protection

Understand PII and implement security measures during onboarding and offboarding.



### Address Security Risk

Address potential technology issues to ensure smooth transition.



# Key Considerations for Contract Closeout from the start

## Part 2



### Ensure File Archival

Ensure all project documentation is appropriately stored and archived. Secure vendor-backed documents to protect sensitive information.



### Reconcile finances and billing

Reconcile finances and finalize invoices to maintain financial integrity.



### Issue termination letters

Ensure vendor and sponsor regulatory compliance, complete invoicing, and fulfill all service obligations, including those extending beyond contract termination.



### Complete contract close-out

Complete contract close-out in our contracting system.



IT Security Team

# Key Planning for External File Repositories

- Do the right personnel have access to the file repositories (e.g., SharePoint or vendor portal)? Who controls vendor access versus sponsor access, and who is responsible for managing it?
- How is access to the repository currently managed and secured to prevent future security risks?
- What backup and recovery processes are in place for closeout, from both the vendor and sponsor?

IT Security Team

# Key Planning to PII and Security

- What measures are in place to safeguard PII throughout the life of the service and post close-out?
- How is access to sensitive data revoked post-termination?
- What procedures exist for securely transferring or destroying PII?



## Top Questions to Ask During Financial Reconciliation of a Contract Closeout

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Have we finished all the services we need from our vendor?

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What is the expected and agreed upon determination date?

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Which invoices have been paid, and which are still outstanding? What are the credits due?

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Are there any accounting issues to address prior to closeout, such as company name changes?

# Example of a Termination Letter



- Clearly state the intention to terminate the contract.
- Include the effective date of termination.
- Mention any obligations that need to be fulfilled before termination such as work stoppage date, final invoicing, and security protocols.
- Mention any obligations that extends beyond the termination of the contract such as confidential information, security, IT decommissioning process, study records, inventions, publications, indemnification and debarment and exclusion survive termination.



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# Effective Communication during close-out activities

Plan	Plan messaging to define reasons for contract closure clearly.
Notify	Notify vendors in advance with formal written notice.
Transparency	Maintain transparency about timelines and final deliverables.
Be Open	Be open to questions and provide a single point of contact.
Documentation	Document all communications and agreements related to closure.
End Well	End on good terms to foster future collaborations.



What comes to mind when thinking about the close-out process?





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## Frequently Asked Questions:

- Who is responsible to tell the vendor?
- How do we deliver the news?
- How early should we plan on telling the vendor that we are closing the services?
- What does a closeout meeting look like?