

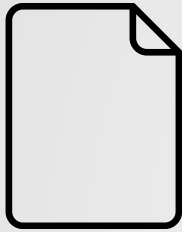


MASTERING TECHNOLOGY COLLABORATIONS IN DIGITAL HEALTH

Best Practice Rules & Insights

TAL KARPLUS - PARTNER | SHIBOLET & CO.
February 18, 2025 | MDI Expo -2025

FROM HEADS OF AGREEMENT TO DEFINITIVE AGREEMENT



Heads of Agreement

Outline key business terms to align expectations early



Non-Binding LOI/MOU/Term Sheet

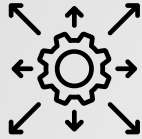
Define preliminary terms, signaling intent without legal commitment



Definitive Agreement(s)

Formalize binding obligations, covering legal, commercial, and operational details

COLLABORATION STRUCTURE AND PRINCIPLES



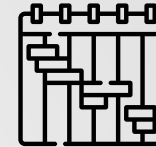
Define Collaboration Scope

Clearly articulate objectives, deliverables, and boundaries



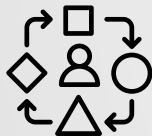
Clarify Roles & Responsibilities

Assign duties with accountability, supported by a detailed RACI matrix



Set Timelines & Commitment Levels

Establish realistic deadlines with flexibility for adjustments



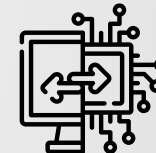
Adapt as Needed

Reassess roles, scope, and timelines to reflect project evolution



Use Plain Language

Ensure clarity to avoid misinterpretations across multidisciplinary teams



Plan for Technology Transfer

Include strategies for seamless integration and knowledge sharing

INTELLECTUAL PROPERTY RIGHTS

Background vs. Foreground IP: Define ownership, usage rights, and licensing for existing and newly developed IP.

Avoid Joint IP Unless Necessary: Joint ownership can complicate enforcement—prefer clear ownership with licensing rights.

Ensure Access to Background Technology: Secure necessary licenses to support collaboration outcomes.

ESTABLISH A GOVERNANCE STRUCTURE

- **Joint Steering Committee:**
Define authority, decision-making processes, and escalation paths.
- **Monitoring & Reporting:**
Implement mechanisms for tracking progress, addressing issues, and maintaining alignment.
- **Agility in Governance:**
Allow for adaptable structures as project needs evolve.

ADDRESS TERMINATION CONDITIONS



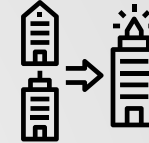
Expiration

Specify conditions under which the agreement naturally concludes



Early Termination

Define triggers, such as breach, insolvency, regulatory issues, market change



Termination for Convenience / M&A

Consider allowing exit under specific conditions, with appropriate notice periods



Post-Termination Obligations

Clarify ongoing duties, like IP rights, confidentiality, and data handling

DATA MANAGEMENT AND SECURITY

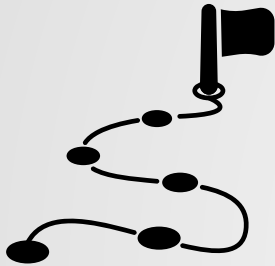
- **Data Ownership & Access:**
Define who controls, accesses, and uses data generated or shared.
- **Privacy & Security Compliance:**
Align with healthcare data laws (e.g., HIPAA, GDPR).
- **Breach Response Plan:**
Establish procedures for detecting, reporting, and mitigating data breaches.



FINANCIAL CONTRIBUTIONS AND COMPENSATION

- **Funding Obligations:**
Specify who funds what, including R&D, regulatory approvals, and operations.
- **Payment Structures:**
Detail milestones, royalties, equity stakes, or cost-sharing models.
- **Audit Rights:**
Allow for verification of financial compliance, especially with royalties or cost reimbursements.

MILESTONES AND PERFORMANCE METRICS



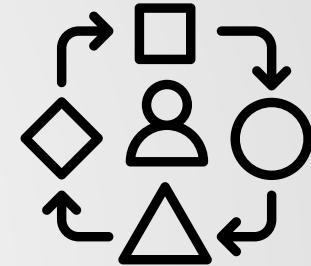
Define Key Milestones

Link payments, deliverables, and success criteria to measurable outcomes



Performance Metrics

Use objective KPIs to track technical, regulatory, and commercial progress



Adaptability

Build in review mechanisms to adjust milestones as the project evolves



LEGAL CONSIDERATIONS

Regulatory Compliance:

Ensure alignment with healthcare, data protection, and industry-specific laws.

Liability & Indemnification:

Clearly allocate risk, with caps where appropriate.

Warranties & Representations:

Define legal and technical assurances, limiting broad or open-ended commitments.

Export Control & Trade Compliance:

Address cross-border data, tech transfers, and sanctions compliance.

REGULATORY CONSIDERATIONS – INVOLVE KEY STAKEHOLDERS EARLY



Engage Regulatory Experts Early

Involve legal, compliance, and regulatory affairs teams from the start to identify potential risks



Anticipate Regulatory Requirements

Consider healthcare-specific regulations (e.g., FDA, EMA, HIPAA, GDPR) that may impact development, data handling, and commercialization



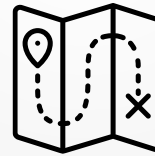
Cross-Border Compliance

Address jurisdictional differences in regulatory frameworks for global collaborations



Integration with Product Development

Align regulatory input with R&D milestones to avoid costly delays



Dynamic Regulatory Landscape

Plan for adaptability to changes in laws, standards, and industry guidelines



Collaborate with External Advisors

When needed, consult with regulatory consultants or authorities to validate compliance strategies

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THANK YOU