Consideration of industry–academia collaboration to conduct studies required for regulatory approval efficiently and effectively in academia.

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【Objective】
To survey barriers to industry–academia collaboration in non-clinical studies for regulatory submissions, and to discuss approaches for enabling efficient and effective collaborative research and commissioned/contracted studies in pharmaceutical R&D.

【Methods】
Surveys of academic researchers and pharmaceutical industry representatives involved in industry–academia collaboration studies

- **Survey A:Pharmaceutical Company Survey**
  - Period: Oct-Nov 2024
  - Target: JSQA member facilities conducting non-clinical pharmacology studies
  - Responses: 67 valid responses from 62 facilities
- **Survey B:Academic Survey**
  - Period: Jun-Jul 2025
  - Target: Academic researchers affiliated with The Japanese Pharmacological Society and Japanese Association for Laboratory Animal Science
  - Responses:9

*Both surveys used web survey system (Qooker)

【Results & Discussion】

<**Barriers to Collaboration**>

① Differences in organizational structure, test procedures and understanding of data reliability

② Insufficient recognition of collaboration benefits

<**Issues**>

① Need for alignment on specific procedures for record standardization, equipment maintenance, and document storage

② Lack of visibility regarding benefits for both academia and company

<**Keys to Successful Collaboration**>

① Explanation, format sharing and close communication from preparation stage

②-1 Companies: Emphasize ability to develop breakthrough drugs using facilities and technologies unique to academia

②-2 Academia: Emphasize access to company compounds and financial resources

<**Benefits of Collaboration**>

① Ensuring data reliability at regulatory requirements level yields valuable data for academic research

② Increased opportunities to secure research funding and publish papers with high impact factors

【Conclusion】
Differences in understanding of data reliability and lack of visible benefits

<**Issues**>
- Standardization, procedure alignment, and value clarification

<**Keys to Successful Collaboration**>
- Close communication from the preparatory stage to the document storage stage
- For companies; it is necessary to emphasize innovative drug development utilizing academic facilities and technologies.
- For academia; it is necessary to emphasize publication opportunities using company compounds and resources.

<**Benefits of Collaboration**>
- Collaboration enables obtaining reliable data, securing research funding and increasing high-quality publication opportunities.

●Close communication to share perception is key to successful study and promoting collaboration
Reference: Guidance on Ensuring the Reliability of Non-Clinical Pharmacology Studies Conducted in Academia
●Collaboration brings significant benefits to both parties

【Summary】

Company Perspective	Academic Perspective
• Concerns about reliability assurance (record formats, raw data management, facility/equipment maintenance) • Concerns about inadequate academic infrastructure	• Differences in understanding test requirements (test procedures, stability information, document storage) • Insufficient explanation from companies
Insufficient effort to explain the 'Reliability Standards'* to academia	Mismatched understandings between company and academia regarding **'test procedures'** and **'data handling'**
Elements considered important to both parties	
• Close communication (alignment during study preparation, sharing of protocols/formats, from the preparatory stage to the document storage stage)	

<**Keys to Successful Collaboration**>
Preliminary explanation + Format sharing + Continuous close communication

<**Benefits**>
Companies: Ability to develop breakthrough drugs using facilities and technologies unique to academia.
Academia: Reduced costs and increased publication opportunities through collaboration.

*:Regulatory standards under Japanese regulatory requirements (the PMDA Act) to ensure the integrity of data submitted for product approval
Key Requirements:
- **Accuracy**: Data must be recorded correctly and precisely
- **Completeness**: All data, including unfavorable results, must be reported
- **Retrievability**: Raw data and source documents must be preserved for verification

The PMDA conducts audits to ensure compliance across the entire process—from study design to final report

Survey questions and responses from survey A and B

Note: "Contract studies" is used here to encompass both collaborative research and commissioned/contracted studies.

Survey A:Pharmaceutical Company Survey

Have you commissioned contract studies to academic institutions in the past 5 years?

Yes:13 (8 facilities)
➡ Key comments:
・Academia has specialized test systems and facilities
・Company simultaneously commissioned clinical trials at the same academic institution
・They conducted collaborative research experiments at the academic institution

No:54 (54 facilities)
➡ Key comments:
・No need for contract studies
・Concerns about ensuring the reliability of the study results and records according to 'Reliability Standards'

Did any unexpected events occur?

Yes:8 | No:5

Stages where unexpected events occurred during the study (multiple responses allowed)
4 Facility inspection
4 Conduct of the study
5 Study records
5 Document storage
6 Others
Events primarily in key reliability assurance stages

Were unexpected events resolved (appropriately addressed)**?**
➡ Most issues (7/8) were resolved by implementing remedial measures
Solutions:
・Company-led study preparation and close communication: Email and web meetings
・Data management and reanalysis for reliability assurance: Reanalysis conducted by company
・Test procedure development and improvement: Procedures manual

Stages of concern regarding contract studies with academic institutions (multiple responses allowed)
9 Facility inspection
8 Planning and preparation of the study
9 Conduct of the study
8 Study records
7 Document storage
13 Others
Concerns primarily in key reliability assurance stages

[Facility inspection]
When facilities and equipment are shared with other laboratories, dealing with just the research partner is insufficient and becomes difficult.
[Planning and preparation of the study]
Templates commonly used in academia often have deficiencies.
[Study records]
Notes are sometimes created separately from worksheets and notebooks, and data is transcribed from these.
[Document storage]
Raw data becomes scattered and cannot be recovered.

Key points and measures for smooth contract studies
➡ Key comments:
・Company's study planning and responsibility structure (sponsor representative) and academia's cooperation (facilities/personnel/technology)
・Thorough advance preparation and close communication
: Coordination between study personnel and quality assurance department
・Sharing records/procedures and quality assurance
: Study record format and equipment maintenance records
Issues were resolved by communicating reliability standard requirements from company

Helpful and appreciated responses from academia
➡ Key comments:
・Academia's cooperative attitude and flexible response: Frequent communication
・Understanding of reliability standards and proper handling of regulatory submissions: Record maintenance and storage
・Added value through collaboration: Network building and future product development

Will you have contract studies with academic institutions in the future? (multiple answers allowed)

Yes:25 | No:41 | No response:1

➡ Key comments:
・No current need to commission studies
・Perceived inability to ensure the reliability of the study

Companies need to consider how to ensure the reliability of contract studies

Tips and considerations for contract studies with academic institutions
➡ Key comments:
・Clarify facility status, storage systems, and ownership
・Systematize operations through SOPs and guideline-based actions
・Ensure reliability via record-keeping and template provision

Survey B:Academic Survey

Have you ever been commissioned by companies to conduct studies?

Yes:7 | No:2

Did any unexpected events or troubles occur?

No:4 | No response:3

Were there any explanations from the company which were insufficient? (multiple answers allowed)

Yes:2 | No:5

➡ **Key comments:**
・Matters related to conduct of the study
・Retention of study records
・Information about test article stability

Will you have company-commissioned studies in the future?

Yes:6
➡ comments:
・To secure research funding
・Anticipated improvements in facility infrastructure by companies and enhanced animal welfare awareness at universities
・Mutual sharing of knowledge and technical expertise through collaborative research was highly beneficial

No:3
➡ comments:
・Lack of an environment suitable for commissioned studies
・Difficulty in meeting 'reliability standards' at present, considering constraints on personnel and cost

Requirements for companies when accepting studies
・Appreciated financial support for facility maintenance
・Proper storage of related documents by the company for future regulatory applications
・More flexibility regarding time and cost requirements.

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COI 開示

☑ 発表内容に関連し，過去３年間，開示すべき COI 関係にある企業などはありません

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