

Executive Briefing
Service Offering for Pre Due Diligence
and Due Diligence Support

Catenion is a management consulting firm devoted to helping pharmaceutical and medical products companies significantly increase the returns on their R&D and Marketing investments by creating more innovative and effective strategies and organisations.

Executive Briefing

Service Offering for Pre Due Diligence
and Due Diligence Support

The Catenion Advantage

- Available when needed
- Independent, rigorous perspective
- Industry best-practice, validated approach and tools
- Experienced team – more than 1,000 R&D projects assessed in-depth across TAs, technologies, and development stages

Driven by the impending patent cliff facing a number of the larger players, as well as by the appetite of new entrants, licensing and M&A activity in the biopharmaceutical space continues unabated.

For each transaction that actually takes place, licensees typically perform up to ten Due Diligences and anywhere between fifty and one hundred Pre Due Diligences – no different to the attrition suffered industry wide.

As the overall industry pipeline of late-discovery, pre-clinical and early clinical projects has expanded, more and more assets need to be assessed by would-be licensors.

The opportunity cost in terms of the time spent by top internal experts away from their day-to-day jobs in line management and on project teams is dramatic, as is the damage done by false negative and false positive decisions to proceed to the Due Diligence stage because of lack of time and attention at the first filter.

Apart from considerations of opportunity cost, speed and objectivity are of the essence; the former can be hampered by the sheer number of opportunities that must be assessed, the latter sometimes falls victim

to the “not-invented-here” syndrome or various pressures to close a particular deal.

Many companies rely occasionally on external expert advice to overcome internal bottlenecks. While experts can certainly provide valuable insights, they often reflect that individual’s personal background and opinion; the problem is that different experts will have different opinions.

Catenion’s approach on the other hand is to systematically review all the evidence and collate legitimate views on the asset’s inherent risks and potential. As a result, the conclusion is as objective as possible.

On this basis, we have developed a clear value proposition on how we can help address the issues our clients face. We use a structured and validated approach to assessing R&D projects and technologies which was originally designed in the context of portfolio management at large pharmaceutical companies.

This approach has been applied in full to well over one thousand assets over the last ten years; it is increasingly being used for Due Diligence and Pre Due Diligence support.

At the **Pre Due Diligence** stage, we alleviate the workload of Business Development Teams by offering a timely, independent recommendation whether or not to proceed to full-scale Due Diligence. Our recommendations are backed up by an unambiguous positioning of the target asset in terms of its risk profile (i.e. compared to relevant industry averages) and commercial potential. Results are documented in the form of a written report and explained via web or telephone conference.

The risk profile of the asset is based on the data available in the public domain and systematically put in the context of data generated by competing compounds in class and/or indication.

For the assessment of commercial attractiveness, we use a validated method of evaluating the innovativeness of the approach in terms of its novelty and usefulness; the result is then factored into a standard, epidemiology-based process of computing ranges of peak patient share and sales potential.

Figure 1: Catenion Pre Due Diligence Services for R&D projects and technology platforms

	Catenion Offering	Approach and Deliverables – Pre Due Diligence
Technical Assessment	ALL PACKAGES	<ul style="list-style-type: none"> Assessment of scientific, medical and clinical rationales based on publicly available information CMC and regulatory aspects covered where relevant For two to three lead indications per R&D project Clear recommendation whether to proceed to Due Diligence stage based on risk profile as measured against relevant industry average, as well as breakthrough potential List of key questions to focus on during Due Diligence
Commercial Assessment	BASE PACKAGE	<ul style="list-style-type: none"> Directional assessment of commercial attractiveness
	COMPREHENSIVE PACKAGE	<ul style="list-style-type: none"> Quantitative assessment of peak sales ranges based on strength of asset profile, unmet need, industry pipeline, epidemiology, as well as expected pricing & reimbursement conditions Not available for technology platforms

Figure 2: Catenion Due Diligence Services for R&D projects and technology platforms

	Catenion Offering	Approach and Deliverables – Due Diligence
Technical Assessment	ALL PACKAGES	<ul style="list-style-type: none"> In-depth, comprehensive risk assessment of asset in data room using proprietary Catenion R&D Risk Assessment Protocol, covering in excess of 500 criteria of risk For two to three lead indications per R&D project Clear assessment of scientific/technical attractiveness as measured against relevant industry average, as well as breakthrough potential
Commercial Assessment	BASE PACKAGE	<ul style="list-style-type: none"> Directional assessment of commercial attractiveness
	COMPREHENSIVE PACKAGE	<ul style="list-style-type: none"> For pre-PoC projects, quantitative assessment of peak sales ranges For post-PoC projects, full forecasting, cost analysis and valuation Both based on strength of asset profile, unmet need, industry pipeline, epidemiology, as well as expected pricing & reimbursement conditions Not available for technology platforms

Our **Due Diligence** support uses the Catenion proprietary tool set including a 500-criteria strong R&D Risk Assessment Protocol and Competitiveness Modeling for full development projects. We accompany client teams into the data room and provide in-depth, full-scale valuations of individual assets and companies. Results are documented in the form of a written report and explained to client in a face-to-face meeting.

In the R&D Risk Assessment Protocol, individual risk criteria are aggregated into six risk classes which are relevant for decision-making: Conceptual Risk, Capability Risk, Compound Risk, Clinical Indication Risk, Product Supply Risk and Regulatory Risk.

All relevant quantitative and qualitative risks are benchmarked against industry average; as a key outcome, the risk profile provides a sound basis for estimating the probability of success for the upcoming development stages.

For full development assets, we assess commercial potential with the help of indication-specific Competitiveness Models, in which we estimate sales potential for both the compound under investigation, as well as for the main competing compounds.

All of our service offerings comprise an in-depth assessment of the scientific and technical merits of the asset; depth of analysis of commercial potential varies from “directional” for the Base Packages to “in-depth” for the Comprehensive Packages (cf. Figures 1 and 2 for an overview of approach and deliverables).

Importantly, our services are fully confidential and not driven by transaction value – see our Executive Briefing

Strategic M&A Support for Pharmaceutical and Biotech Companies –minimising the risk of “Winner’s Curse”.

Due Diligence recommendations and asset valuations are based on the intrinsic merits of the assets under analysis; while we provide a directional opinion as to strategic fit with client strategy and pipeline, a formal evaluation of this dimension is not part of our standard offer.

All content is provided "as is", without warranty of any kind, either express or implied, including, without limitation, implied warranties of merchantability and fitness for a particular purpose. Catenion and its third-party content providers make no warranties, express or implied, as to the ownership, accuracy, or adequacy of the content. Neither Catenion nor its third-party content providers shall be liable for any indirect, incidental, consequential, or punitive damages or for lost revenues or profits, whether or not advised of the possibility of such damages or losses and regardless of the theory of liability.

Catenion GmbH, Hausvogteiplatz 12, 10117 Berlin – HRB95394 b, Geschäftsführer: Dipl.-Ing. Arno Heuermann



Content is licensed under a Creative Commons: Attribution (No Derivative Works 3.0), www.creativecommons.org/licenses/by-nd/3.0

Executive Briefing
Service Offering for Pre Due Diligence
and Due Diligence Support

Berlin

Catenion
Hausvogteiplatz 12
10117 Berlin
Germany
phone: +49 30 2063 996 – 0
fax: +49 30 2063 996 – 22
email: berlin@catenion.com

New York

Catenion
405 Lexington Avenue, 26th Floor
New York, NY 10174
United States
phone: +1 212 203 7276
fax: +1 917 368 8005
email: newyork@catenion.com

London

Catenion
180 Piccadilly
London W1J 9HF
United Kingdom
phone: +44 20 7917 9511
fax: +44 20 7439 0262
email: london@catenion.com

Tokyo

Catenion
Level 20 Marunouchi Trust Tower
1-8-3 Marunouchi, Chiyoda-ku
Tokyo 100-0005 Japan
phone: +81 35288 5270
fax: +81 35288 5271
email: tokyo@catenion.com

www.catenion.com