Information from the Target During Due Diligence Review

1. Identities (operating names of the target and its affiliates, company numbers, jurisdiction, certificates)
2. Third Parties (strategic partners, alliances, identities, locations)
3. Competition Analysis (in the relevant market)
4. Target's Business Plan and Marketing Plans
5. Counsel (for the target (or the asset owner) on IP matters)
6. Issued Patents (active and expired)
7. Patent Applications Worldwide (pending, published, or other) [country, application date, registration date, status, expiration date, owner, nature of interest, identity and identifiers]
8. Patent Proceedings (pre-issuance proceedings, oppositions, re-issues, re-examinations, post-grant proceedings)
9. Impediments (potential and include publications)
10. Encumbrances (pledges, liens on any patent or technology or substance)
11. Global Asset List (including the technologies, products and processes on the market or under development and associated patents)
12. Development Reports (for methods or materials or substances)
13. Unprotected Assets (technology, products, processes with no patent protection)
14. Legal Opinions (patentability, validity, and infringement opinion)
15. Publications and Disclosures (content, forum and date) involving the target's products, processes or technology
16. Agreements (license agreements, supply or distribution agreements, development agreements, collaborative, sponsored research, contract research agreements, CDAs, transfer agreements, employee and consulting agreements), target’s policy statements on intellectual property (maintenance of invention, commercialization, laboratory files, conflicts policy)
17. Disagreements (disputes, litigation, involving infringement, validity or rights in target’s IP, other relevant IP, and resolutions if any)
18. Therapy Area Experts (reports on patient groups, treatment modalities)
19. Surgeons (information on e.g. feasibility, or, other opinion)

20. Patient Associations (reports, consultations, other inputs)
21. HCP (reports, consultations, other inputs)
22. Nonclinical Studies (reports & documents including not in MA dossier)
23. Clinical Trials (reports & documents including not in MA dossier)
24. Marketing Authorisations (e.g. FDA, EU Commission and associated opinion, conditions, obligations, reports, renewals, variations, letters)
25. PV Inspection correspondences
26. Manufacturing (scope of MA, site inspection correspondences, process development, cell/tissue donation, starting materials, transmissible agents, GMP issues)
27. ASMF details
28. Companion Diagnostic details
29. Drug Delivery Device details
30. Product Regulatory Designations, e.g. orphan, breakthrough, fast-track
31. PIP and WR (Opinion, Decision, modifications, Request, correspondences)
32. IND submissions and correspondences
33. CTA submissions and correspondences
34. Third country licenses and CPP issued for use in third countries
35. Scientific Advice Procedures (dossiers, letters, Minutes, other)
36. Product Information (target's regulated product information that exists in the public domain, worldwide)
37. Documents pursuant to the *EMA Access To Documents Policy* (e.g. biopharmaceutics, bioavailability, studies on human biomaterials, *in vivo* and *in vitro* correlation, mass balance, plasma binding, drug interactions, method development and method validation)
38. FOI Documents Worldwide (proprietary information via regulatory agencies)
39. Investors (including grants) for the development plans of the target
40. Meeting Minutes. **(Do not rely on the documents alone. Discuss them with the target company staff and its consultants. Document all discussions for the record. Issue a confidential copy of the record in a timely manner to the specific participants.)**
41. Budget and Billing (consultancy contracts, time and tasks)