

Explanatory Notes for the PCP Framework Agreement

Article	Text	Additional information/interpretation
8.2.	Procurers are entitled to carry out a visit to the Contractor's premises at any time for the purpose of due diligence and evaluation in respect of the Project.	Such a visit would be subject to reasonable prior notice and conducted during normal business hours. Confidentiality obligations of the Contractor towards third parties must not be breached and Contractor's data security or trade secrets must not be infringed during such a visit. Procurers bear the costs of such a visit.
9.2.	The Contractor shall meet, with time being of the essence, delivery in any performance dates, including but not limited to End of Phase Reports and related deliverables. If the Contractor fails to do so, the Lead Procurer may, after giving the Contractor not less than 14 Days' notice of its intention (without prejudice to any other rights it may have): (a) terminate this Agreement in whole or in part without liability to the Contractor; (b) refuse to accept any subsequent performance of the PCP Project which the Contractor attempts to make; (c) hold the Contractor accountable for any loss and additional costs incurred; and (d) have all sums previously paid by the Lead Procurer to the Contractor under the Phase which is then running, refunded by the Contractor.	If there are any failures in sight during the PCP Project there will be an interactive assessment and process to define corrective actions before any further steps are taken.
9.2.c	(c) hold the Contractor accountable for any loss and additional costs incurred	Read in conjunction with Article 24.5.
9.3.e	The Contractor shall: (e) not make any changes to the Contractor Representative, subcontractors or the key staff without the prior written approval of the Lead Procurer, such approval not to be unreasonably withheld or delayed	If the proposed Contractor Representative, subcontractors or the key staff are suitably qualified and the requirements of the Framework Agreement (e.g. Article 5.2., 28.4.) are complied with the Lead Procurer cannot withhold approval of the changes.

9.3.i	The Contractor shall: (i) acknowledge and adjust to any modification with respect to the Technical Offer as mentioned in Article 7 of this Framework Agreement	Read in conjunction with Article 7.2 (mutual agreement by the Parties). See also Article 7.5.
9.4.	The Contractor acknowledges and agrees that the Contractor is entering into this Framework Agreement on the basis that the details of the PCP Project are accurate and complete in all material respects, and are not misleading.	The Contractor confirms that at the time of signing the Framework Agreement the details of the PCP Project are accurate and complete in all material respects, and are not misleading.
10.9.	During the Project Period payments will be made by the Lead Procurer pursuant to invoices issued to the Lead Procurer. The Lead Procurer may suspend this payment at any time if, in the view of the Lead Procurer, acting reasonably, satisfactory progress on the PCP Project has not been maintained, or reports have not been submitted as required under Article 8.	See additional information to Article 9.2. above.
10.11.	Subject to the confidentiality obligations set forth in Article 15, the Contractor grants to the Lead Procurer, acting, as the case may be, through agents authorized for that purpose, and to any statutory or regulatory auditors of the Lead Procurer, a right to access (and, if necessary to copy) the relevant financial records during normal business hours.	See additional information to Article 8.2. above.
11.3.	The Contractor will provide each of the Procurers an irrevocable, indefinite, worldwide, royalty-free and non-exclusive license to use all Pre-existing rights and Sidegrounds that are needed to perform the PCP Project for the purpose of executing the PCP Project as well as for using the Results for further non-commercial research purposes, including clinical trials set up to test the validity of the Results.	Regarding Results that constitute software this clause does not mean that maintenance and updates must be provided indefinitely, if the software is no longer used for plausible reasons.
12.1.	Subject to Article 13 and 14, the ownership of Results shall remain with the Contractor. The Contractor will provide each of the Procurers an irrevocable, indefinite, worldwide, royalty-free and non-exclusive license to use the Results for non-commercial research purposes, teaching and patient care. In case of Results that constitute software, the non-commercial research license will extend to all updates and upgrades	Non-commercial also refers to patient care, which however has to comply with IVDR. Therefore, patient care most likely will only be relevant in context of clinical research. The license provided to the Procurers under Article 12.1 regards to Results of the Contractor. According to Article 1 (ee) of the Framework Agreement Results (i.e. foreground) are defined as

	thereof.	<p>any tangible or intangible output, such as data, knowledge or information, that is generated in the PCP Project, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including Intellectual Property Rights. Therefore, this Article does not refer to Intellectual Property Rights of third parties. However, see 28.2 for subcontractors.</p> <p>If the development of software is part of the R&D Services provided by the Contractor, the software is part of the Results.</p>
12.3.	If the Contractor does not seek protection for Results, the Procurers have the right to request (via the Lead Procurer) that the Results are transferred to them on fair and reasonable market conditions subject to a separate agreement to file for protection.	This clause only applies to Results that can be protected (e.g. as patents) and not to Results that are automatically protected by copyright law (e.g. software). See also Article 13.3.
12.4.	The Lead Procurer shall have the right to grant or to require the Contractor to grant non-exclusive licenses to third parties to exploit the Results, including the Pre-existing rights and Sidegrounds that are needed to perform the PCP Project/use the Results under fair and reasonable market conditions without any right to sublicense. The Contractor and these third parties are responsible for establishing the fair and reasonable market conditions.	<p>This clause arises from the EU Grant Agreement. It is necessary as IPR ownership rights remain with the Contractors participating in the PCP. This however, must not give the Contractors any form of unfair advantage in a possible future PPI.</p> <p>The licenses to third parties under 12.4. are granted under fair and reasonable market conditions that are established between the Contractor and the third parties. See also the definition of “Fair and reasonable market conditions” in Article 1 (m): Appropriate conditions, including financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access (for example, the actual or potential value of the Results or Pre-existing rights to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged).</p>
13.8.	The Contractor is aware and it shall ensure that the EU have special rights (e.g. protection of the Results and EU ownership).	See Article 16.11., 16.12. and 16.13.

22.2.	Should there be an on-the-spot visit by the EU, the Contractor must allow access to its premises and must ensure that the information requested is readily available.	The obligations under Article 22 originate from the EU Grant Agreement and also apply to the Contractors.
23.	Should the EU carry out an impact evaluation (of its grant to the Procurers), the Contractor must make available all information, records and other supporting documents relating to the implementation of the Framework Agreement and Specific Contracts.	The obligations under Article 23 originate from the EU Grant Agreement and also apply to the Contractors.
24.3.	If the Contractor fails to deliver Results or other deliverables compliant or breach the other obligations with the Framework Agreement, the Lead Procurer shall give the Contractor the opportunity to amend, within an appropriate period. If the Lead Procurer is still not satisfied after the expiry of such cure period it may (at its discretion): <ul style="list-style-type: none"> (a) withhold payments until satisfactory delivery; (b) cancel payments; (c) exclude the Contractor from the/any subsequent Phases on the basis that the Contractor has not successfully completed the present Phase; and/or (d) terminate the Framework Agreement and/or any Specific Contract (see hereunder). 	See additional information to Article 9.2. above. The Request for Tender (integral part of the Framework Agreement) lays down the requirements for satisfactory completion on page 103f.
24.4.	Acceptance by the Lead Procurer of any deliverable or Result shall not limit the Contractor from liability in respect of such deliverable or Result subsequently being discovered to be non-compliant with the requirements of the Framework Agreement, nor for any loss or damage which may arise as a result.	This clause does not mean that there will be a reopening of the evaluation process conducted according to Article 6. It would be applicable if e.g. any violation of IP by the Contractor is discovered later.
24.5.	Except in case of infringement of applicable laws, gross negligence or wilful misconduct on its part, a Party shall not be liable to the other for loss of the Framework Agreement, loss of income or revenue, loss of customers or reputation or any other indirect or consequential loss or damage.	The Contractor is liable for damages arising from or in connection with its acts or omissions in relation to the Framework Agreement or Specific Contract. Use of the Results by the Procurers after the project for their own non-commercial purposes is the responsibility of the Procurers.



		The applicable law is defined in Article 29.
24.8.	The Contractor must compensate the Procurers if they are held liable by the EU for damage sustained as a result of the implementation of the Framework Agreement or a Specific Contract or because it was not implemented properly.	Article 24.8. relates to damages suffered by the EU because of the PCP Project as a whole.