Algemene informatie

Aanbesteding: EA Neoantigen Peptides for therapeutic purpose
Aanbestedende Dienst: Erasmus MC
Referentie: -

Toelichting:

Vraag en antwoord

Ref.nr. 1

Onderwerp:
Language of documents and submission

Vraag:
Despite significant effort, we are unable to submit an application to tender unless documentation is provided in English. We do not want to build assumptions into our proposal that have arisen from translated documents. Please provide documentation for submission in English. Thank you

Antwoord:
Not all documentation is available in English. Nevertheless, the requirements, specifications, and pricing sheet have been translated and submitted as a new annex.

Fase:
Inschrijffase

Inschrijfronde:
Inschrijfronde 1

Vragenronde:
Vragenronde 1

Percelen: P1 EA Neoantigen Peptides for therapeutic purpose

Beantwoord op: 16 okt 2025

Ref.nr. 2

Onderwerp:
Peptide quantities

Vraag:
There seems to be inconsistencies in the descriptions for the required quantity of individual peptides. Can you confirm that you need 12 mg net of each peptide (as opposed to gross) to be available for mixtures (excluding

quantity for release)?

Antwoord:
Yes, a total of 12 mg net per peptide is required for the peptide pooling phase. For peptide pooling, 12 mg net weight is required for each peptide. Therefore, at the individual peptide stage a minimum of 12 mg is required (which can either be gross or net, but is now defined as gross).

Fase:
Inschrijffase

Inschrijfronde:
Inschrijfronde 1

Vragenronde:
Vragenronde 1

Percelen: P1 EA Neoantigen Peptides for therapeutic purpose

Beantwoord op: 16 okt 2025

Ref.nr.
3

Onderwerp:
Net content specification

Vraag:
Can you confirm that theoretical peptide content is your only measure of net peptide requirements. That is to say, you are not expecting to adjust for purity?

Antwoord:
Correct

Fase:
Inschrijffase

Inschrijfronde:
Inschrijfronde 1

Vragenronde:
Vragenronde 1

Percelen: P1 EA Neoantigen Peptides for therapeutic purpose

Beantwoord op: 16 okt 2025

Ref.nr.
4

Onderwerp:
Pooling strategy

Vraag:
You have stated that the pooling strategy must be proposed by the manufacturer. We would like to more fully understand the scope of this statement whether this relates to the pooling process itself, or the selection of which peptides are to be included in the pool, or both.

Antwoord:
It relates to both the pooling process and the selection of which peptides to be included per pool. As stated, the strategy should be proposed by the manufacturer and should be approved by EMC prior to performing the handlings.

Fase:
Inschrijffase

Inschrijfronde:
Inschrijfronde 1

Vragenronde:
Vragenronde 1

Percelen: P1 EA Neoantigen Peptides for therapeutic purpose

Beantwoord op: 16 okt 2025

Ref.nr.
5

Onderwerp:
Annex 1 success criteria clarification

Vraag:
In Annex 1, the success criteria for the “wishes program” has a burden upon disclosing historical, and client confidential, data. We would like to better understand how EMC would like how to demonstrate that we meet these criteria without sharing this confidential information. Would EMC comment on this?

Antwoord:
For us the privacy-sensitive information is not of importance. The required information can be disclosed in an anonymized manner (e.g. based on averages and standard deviations).

Fase:
Inschrijffase

Inschrijfronde:
Inschrijfronde 1

Vragenronde:
Vragenronde 1

Percelen: P1 EA Neoantigen Peptides for therapeutic purpose

Beantwoord op: 16 okt 2025

Ref.nr.
6

Onderwerp:
Purity criteria clarification, Annex 1

Vraag:
In Annex 1, there appears to be an inconsistency between the specifications that EMC is expecting the manufacturer to meet. That is to say, the requirement is that peptides are produced to 90% by LC, but the “wishes program,” ask the manufacturer to demonstrate >95% purity for both peptides and pools. Would EMC provide clarity on this topic?

Antwoord:
The 90% purity requirement by LC is the minimum mandatory specification for the peptides. The >95% purity mentioned in the “Wishes Program” represents a desired target, which allows for additional points to be awarded for higher quality. In other words, 90% is the required minimum, while 95% or higher is considered a quality bonus.

Fase:
Inschrijffase

Inschrijfronde:
Inschrijfronde 1

Vragenronde:
Vragenronde 1

Percelen: P1 EA Neoantigen Peptides for therapeutic purpose

Beantwoord op: 16 okt 2025

Ref.nr.
7

Onderwerp:
T&C clarification and comments

Vraag:

Is Erasmus MC open to discussing T&Cs with the bidder to reach mutually agreeable terms and conditions for the work described in the bid? If so, can the bidder provide comments and/or a redline of the T&Cs presented in the tender documents?

Antwoord:
We hereby inform you that it is not possible to discuss the General Terms and Conditions (AIV) substantively outside of the tender process. However, the bidder is invited to submit any comments or proposed changes to specific articles of the AIV via Information Notice 2 (NVI2).

Fase:
Inschrijffase

Inschrijfronde:
Inschrijfronde 1

Vragenronde:
Vragenronde 1

Percelen: P1 EA Neoantigen Peptides for therapeutic purpose

Beantwoord op: 16 okt 2025

Ref.nr.
8

Onderwerp:
Shipment

Vraag:
Regarding product shipping, EMC has asked that the product is shipped to them according to GDP standards. This is not a typical requirement for drug substance. We would like to engage further with EMC regarding this, would this be possible?.

Antwoord:
The DS is required to be shipped according to GDP standards. This is a mandatory requirement and cannot be negotiated. Therefore, further discussion regarding this requirement will not be possible.

Fase:
Inschrijffase

Inschrijfronde:
Inschrijfronde 1

Vragenronde:

Vragenronde 1

Percelen: P1 EA Neoantigen Peptides for therapeutic purpose

Beantwoord op: 16 okt 2025

Ref.nr.
9

Onderwerp:
Sterility testing requirement clarification

Vraag:
According to Annex 1, there is a requirement for the peptide pool(s) (the drug substance) to be tested for sterility. We cannot provide sterile products, and it is our experience that this is a specification test for of the drug product, and not the drug substance which we would provide. Typically, we would test drug substance for bioburden to an agreed specification. Would EMC engage in discussions around this topic, leveraging our expertise in this field?

Antwoord:
For us, this is a semantic discussion, and we would like to clarify our needs. It is important that the bioburden of the DS is below 1 CFU.

Fase:
Inschrijffase

Inschrijfronde:
Inschrijfronde 1

Vragenronde:
Vragenronde 1

Percelen: P1 EA Neoantigen Peptides for therapeutic purpose

Beantwoord op: 16 okt 2025

Ref.nr.
10

Onderwerp:
TFA specification clarification

Vraag:
We agree with the testing strategy of measuring TFA content in the final product pool. However, we would encourage EMC not to set a specification on TFA content and proceed with report result. Would EMC be open to discussion on this specification?

Antwoord:

No, we believe a specification for the TFA content is required.

Fase:
Inschrijffase

Inschrijfronde:
Inschrijfronde 1

Vragenronde:
Vragenronde 1

Percelen: P1 EA Neoantigen Peptides for therapeutic purpose

Beantwoord op: 16 okt 2025

Ref.nr.
11

Onderwerp:
Impurity specification clarification

Vraag:
It is unusual for neoantigen targeting peptide pools to have the specification of <1% for a single impurity, as this necessitates a further point of control at the individual peptide release, which may have attritional implications. Is EMC open to discussions around this specification?

Antwoord:
For us it is important that no impurities of >1% are present within the peptide pool. This is not up for discussion. It is up to the tenderer to determine how to meet this requirement (including whether each peptide should be tested individually).

Fase:
Inschrijffase

Inschrijfronde:
Inschrijfronde 1

Vragenronde:
Vragenronde 1

Percelen: P1 EA Neoantigen Peptides for therapeutic purpose

Beantwoord op: 16 okt 2025