



EUROPEAN COMMISSION

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Mr Leonid Schneider
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Germany

**DECISION OF THE EUROPEAN COMMISSION PURSUANT TO ARTICLE 4 OF THE
IMPLEMENTING RULES TO REGULATION (EC) NO 1049/2001¹**

**Subject: Your confirmatory application for access to documents under
Regulation (EC) No 1049/2001 - Gestdem 2018/4723**

Dear Mr Schneider,

I refer to your e-mail of 19 October 2018, registered on 22 October 2018, in which you lodge a confirmatory application in accordance with Article 7(2) of Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents² (hereafter: 'Regulation 1049/2001').

1. SCOPE OF YOUR APPLICATION

On 28 August 2018, you submitted an application for access to documents containing information regarding the Intestinal Tissue Engineering Solution³ project, which is partly financed through the European Union's Horizon 2020 research and innovation programme.

In your application, you pointed out that '[t]he U[niversity]C[ollege]L[ondon]-led clinical trial INTENS and Dr Paolo De Coppi (famous for his trachea transplants with Paolo Macchiarini and Martin Birchall) announced, as Work Package 5 [of the Intestinal Tissue Engineering Solution project], the "transplantation of engineered intestine" in patients, [that is planed] to take place at U[niversity]C[olege]L[ondon] [...] and in U[niversity] [of] C[alifornia] L[os] A[ngeles] [...]'. You underline that '[t]he project started in 2016, hence [you] request a status update on:

¹ Official Journal L 345 of 29.12.2001, p. 94.

² Official Journal L 145, 31.05.2001, p.43.

³ INTENS.

- any issued ethical approvals for clinical trials on patients,
- any approvals issued by E[uropean] M[edicines] A[gency],
- any recruiting clinical trials,
- any transplantations already performed’.

Your application was attributed to the Directorate-General for Research and Innovation.

On 17 October 2018, the Directorate-General for Research and Innovation provided its reply to your application, in which it informed you that the European Commission does not hold any documents that would fall under the scope of your application. Indeed, as underlined by the Directorate-General for Research and Innovation, the Intestinal Tissue Engineering Solution project does not envisage any deliverables related to clinical trials on patients under Regulation 536/2014⁴ to be provided to the European Commission. Consequently, the European Commission is not in a position to handle your application.

On 18 October 2018, you submitted a confirmatory application, in which you contest the position of the Directorate-General for Research and Innovation.

2. ASSESSMENT AND CONCLUSIONS UNDER REGULATION 1049/2001

When assessing a confirmatory application for access to documents submitted pursuant to Regulation 1049/2001, the Secretariat-General conducts a fresh review of the reply given by the Directorate-General concerned at the initial stage.

Following your confirmatory application, the European Commission has carried out a renewed, thorough search for the documents requested. Following this renewed search, I confirm that the European Commission has not identified any documents to which you refer in your confirmatory application.

In line with the provisions of Article 2(3) and Article 10 of Regulation 1049/2001, the right of access guaranteed by that Regulation applies only to existing documents in possession of the institution concerned.

Article 2(3) provides that ‘[t]his Regulation shall apply to all documents held by an institution, that is to say, documents drawn up or received by it and in its possession, in all areas of activity of the European Union’.

Article 10(3) provides that ‘[d]ocuments shall be supplied in an existing version and format [...]’.

In the light of the above, given that the European Commission does not hold any documents such as the one mentioned in your confirmatory application, it is not possible to handle your application.

⁴ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, Official Journal, L 158, 27.5.2014, p. 1–76.

3. ASPECTS FALLING OUTSIDE THE ASSESSMENT UNDER REGULATION 1049/2001

In your confirmatory application, you refer to the website of the Intestinal Tissue Engineering Solution project⁵ and point out that, according to the information available therein, '[t]he work package 5 is titled: "Transplantation of engineered intestine"'. You also add that '[you] reached out to members of the consortium [implementing the Intestinal Tissue Engineering Solution project] and received no information about that work package [...]'. According to your confirmatory application, that was the reason why you submitted your 'request [for access to documents] to the [European] Commission'. Furthermore, you underline that '[o]ne of the goals of Intestinal Tissue Engineering Solution [project] is defined: "Engineering intestine for transplantation"' and refer to the information available on the website of the European Commission, which in your view 'declares [that] "The work is designed to lead directly to a clinical trial for the application of the optimal protocol for tissue-engineered intestine."'

Consequently, '[you] request the E[uropean] Commission to study the original grant proposal [of the Intestinal Tissue Engineering Solution project], find the section about the scheduled clinical applications, contact the Consortium lead at U[niversity]C[olege]L[ondon] and inform [you] on any clinical applications of [the Intestinal Tissue Engineering Solution] bowel replacements which already took place or are scheduled either in a clinical trial or as compassionate use.'

Please note, however, that the description of the work programme of the Intestinal Tissue Engineering Solution project, available on the website to which you refer in your confirmatory application (see footnote 5), clearly provides that 'The project will first optimize the derivation, culture and differentiation of cells and seed on decellularised scaffolds or synthetic polymers and maintained in bioreactors (WP1-3)'. It is underlined in the programme of the project that only 'Once established, the project will focus on *in vivo* testing in animal models (WP4-5)'. The output of the the Intestinal Tissue Engineering Solution project 'will provide the foundations of the post project activities to achieve G[ood] M[anufacturing] P[ractices] production and conduct a clinical trial. During the entire project (WP6-7), we will also continue to engage with patients' associations, their families, and the European Medicines Agency to promote our research and prepare the regulatory requirements to make the basis for the subsequent clinical trial.'

Consequently, no clinical trials are envisaged in the grant agreement of the Intestinal Tissue Engineering Solution project and therefore the European Commission does not hold any related documents concerning 'ethical approvals for clinical trials on patients', 'approvals issued by E[uropean] M[edicines] A[gency]', 'recruiting clinical trials' or 'transplantations already performed' under Regulation 536/2014.

As mentioned above, the Intestinal Tissue Engineering Solution project is currently focused on *in vivo* testing in animal models. The deliverables of work package 5, "Transplantation

⁵ <http://www.intens.info/project/workplan/> and <http://www.intens.info/wp-content/uploads/2016/06/Diagram-WPs-768x485.jpg>.

of engineered intestine", are research analysis of TEI in mice, outcome and function of TEI in piglets and outcome and function of TEI in short bowel syndrome piglets.

The results of this research, with the other envisaged project results, will provide the foundations for the future clinical trial projects.

4. MEANS OF REDRESS

Finally, I would like to draw your attention to the means of redress that are available against this decision. You may either bring proceedings before the General Court or file a complaint with the Ombudsman under the conditions specified respectively in Articles 263 and 228 of the Treaty on the Functioning of the European Union.

Yours sincerely,



*For the Commission
Martin SELMAYR
Secretary-General*