Low intervention clinical trials

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MINISTERIO DE SANIDAD
agencia española de medicamentos y productos sanitarios

Regulation (EU) N° 536/201

A CT that fulfils all of the following conditions:

(a) the investigational medicinal products (IMP), excluding placebos, are authorised;

Low Intervention CT Art. 2 (3)

Regulation (EU) N° 536/201

A CT that fulfils all of the following conditions:

(b) according to the protocol of the CT,

(i) the IMPs are used in accordance with the terms of the marketing authorisation; or

Low Intervention CT Art. 2 (3)

Regulation (EU) N° 536/201

A CT that fulfils all of the following conditions:

(b) according to the protocol of the CT,

(i) the IMPs are used in accordance ~~with the terms of the marketing authorisation; or~~

(ii) the use of the IMPs is evidence-based and supported by published scientific evidence on the safety and efficacy of those IMPs **in any** of the ~~Member States concerned; and~~

Low Intervention CT Art. 2 (3)

Regulation (EU) N° 536/201

A CT that fulfils all of the following conditions:

(ii) the use of the IMPs is evidence-based and supported by published scientific evidence on the safety and efficacy of those IMPs **in any** of the ~~Member States concerned; and~~

Low Intervention CT Art. 2 (3)

(Whereas 11) …**published scientific evidence** supporting the safety and efficacy of an IMP not used in accordance with the terms of the marketing authorization **include high quality data published in scientific journal articles, national, regional or institutional treatment protocols, health technology assessment reports or other appropriate evidence.**

Regulation (EU) N° 536/201

A CT that fulfils all of the following conditions:

(ii) the use of the IMPs is evidence-based and supported by published scientific evidence on the safety and efficacy of those IMPs **in any** of the ~~Member States concerned; and~~

Low Intervention CT Art. 2 (3)

(Art.5) 2. **The sponsor shall**, when applying for a LICT, …., **propose one of the MS concerned where the use is evidence-based, as reporting MS.**

Regulation (EU) N° 536/201

A CT that fulfils all of the following conditions:

(c) the additional diagnostic or monitoring procedures **do not pose more than minimal additional risk or burden** to the safety of the subjects **compared to normal clinical practice ~~in any Member State concerned~~;**

Low Intervention CT Art. 2 (3)

Regulation (EU) N° 536/201

A CT that fulfils all of the following conditions:

(c) the additional diagnostic or monitoring procedures **do not pose more than minimal additional risk or burden** to the safety of the subjects **compared to normal clinical practice ~~in any Member State concerned~~;**

Low Intervention CT Art. 2 (3)

Examples of minimal additional burden:
measuring height and/or weight, questionnaires, analysis of saliva, urine, stool samples, EEG and ECG measurements, blood withdrawal through a pre-existent catheter or with minimal additional venipuncture.
(Eudralex vol 10: Risk proportionate approaches in CT)

Risk proportionate approaches in clinical trials Eudralex - volume 10

- Adverse events recording and reporting (as per protocol)
- Traceability and accountability
- Clinical trial monitoring
- Content of the Trial Master File
- Insurance

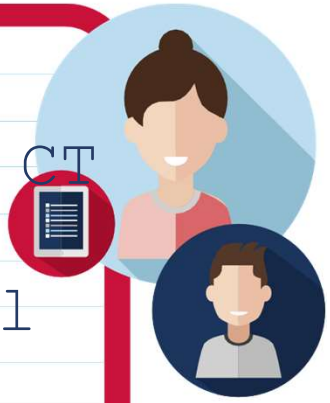
Low intervention CT in Spain until 28th Feb 2021

191 LICT since 1st Jan 2016

4.3% of authorised CT

94.8% non Commercial

89.5% National



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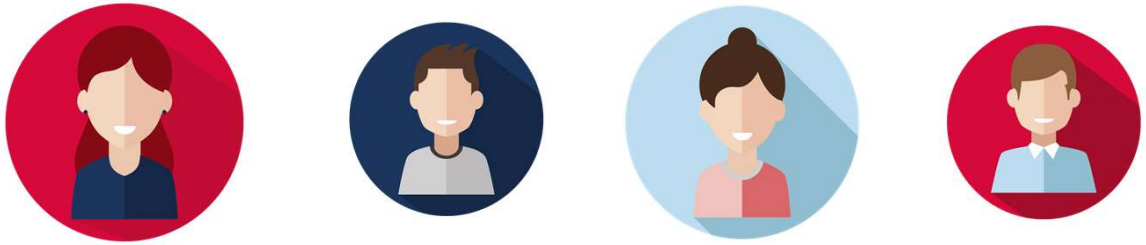
Thank you very much!



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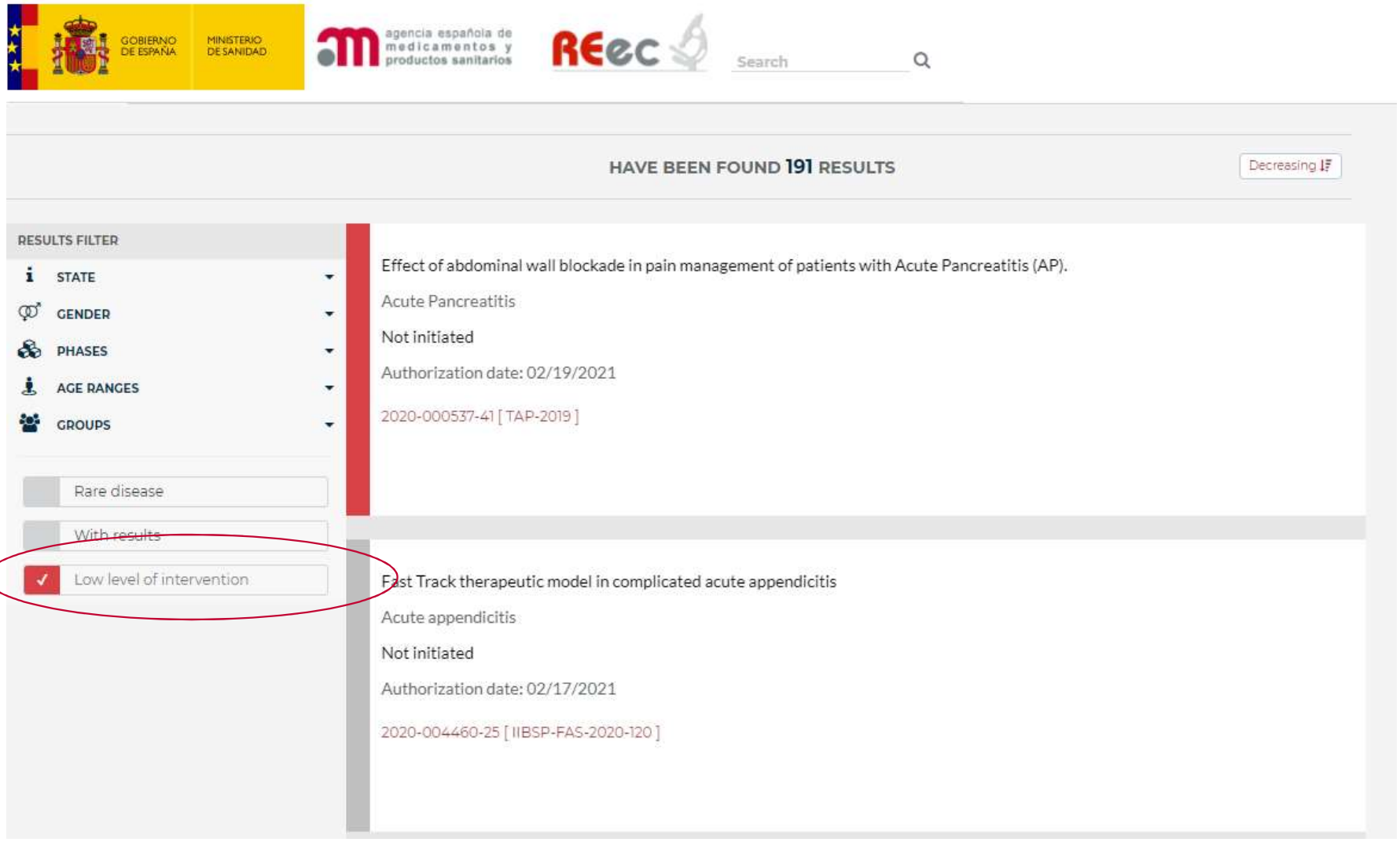
(Whereas 11) ….. LICT are often of crucial importance for assessing standard treatments and diagnoses, … contributing to a high level of public health.

They should be subject to less stringent rules ….

(Whereas 11) ….LICT should be subject to the same application procedure as any other CT.

Annex I The cover letter shall indicate if the CT is considered to be a LICT and shall contain a detailed justification thereof.



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