SUMMARY PROTOCOL

REGISTRY OF THE SPANISH SOCIETY OF THORACIC SURGERY

SOCIEDAD ESPAÑOLA DE CIRUGÍA TORÁCICA

October 2022

Content

1. Justification

The Spanish Society of Thoracic Surgery (SECT) is a scientific society founded in 2007 and constituted for an indefinite period whose objective is to contribute to the progress of thoracic surgery in all its aspects, promoting training, development, and professional improvement of thoracic surgeons, seeking the best quality in patient care, and promoting teaching and research (1).

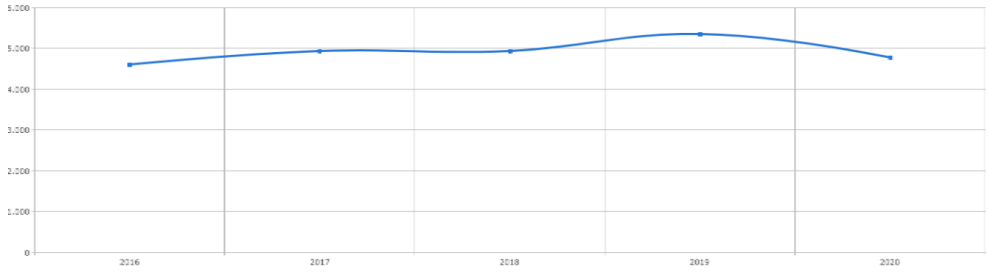
One of the objectives of the SECT since its inception has been to promote research by carrying out multi-center projects to foster both experimental and basic research, as well as clinical research in the most rigorous way possible.

The Registry of the Spanish Society of Thoracic Surgery is a project promoted by the Board of Directors of our society whose initial design began in January 2022. ReSECT project aims not only to become an indefinite, dynamic and inclusive registry of the Spanish thoracic surgery, but also to establish a common structural framework for the development of multicenter projects. Despite this common structural basis, the incorporation of such future multicenter studies will be subject to the corresponding approval by an accredited clinical research committee.

The data model of the current ReSECT project derives partially from the model used by the Spanish Group of Video-Assisted Thoracic Surgery (GEVATS), which was established as a SECT working group in 2015. It is a multicenter group made up of 33 national thoracic surgery services whose main objective was to analyse the impact of the surgical approach on postoperative morbidity and mortality after anatomical pulmonary resection, and oncological prognosis after this technique in the subgroup of patients operated on for lung cancer (2).

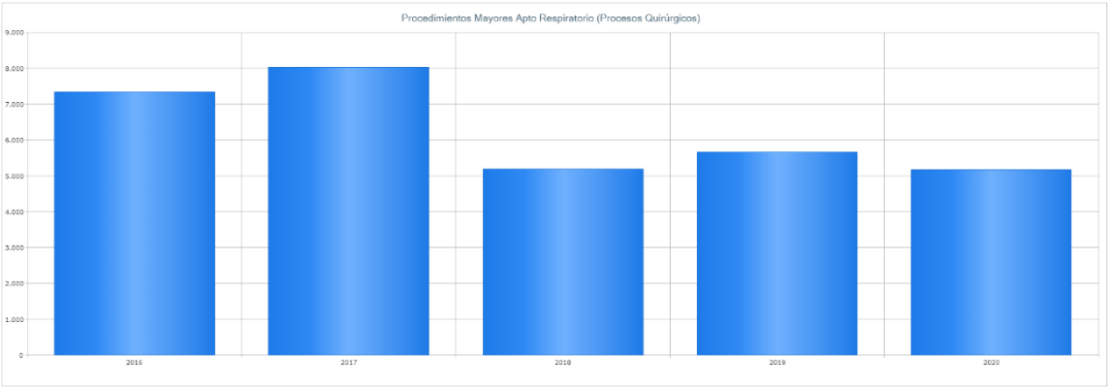
Based on figures published by the Spanish Ministry of Health on the number of major lung resections performed by the national thoracic surgery services, the GEVATS sample (3533 patients in 15 months) represented approximately 53% of the major lung resections performed in Spain during the recruitment period. This type of surgical procedure accounts for most major surgical procedures performed on the respiratory system.

Despite this remarkable representativeness, one of the main limitations of the GEVATS has to do with the limited time frame in which it was developed and, consequently, its inability to carry out continuous quality control through adequate analysis techniques. On the other hand, the limited number of patients per surgical department (median 100 patients and p25-p75 68-136 patients) did not allow robust conclusions to be drawn on performance for inter-institutional benchmarking purposes. We believe that the current ReSECT project can overcome both limitations and represent a turning point in national thoracic surgery research.



Annual number of major pulmonary resections performed by Thoracic Surgery Services in Spain

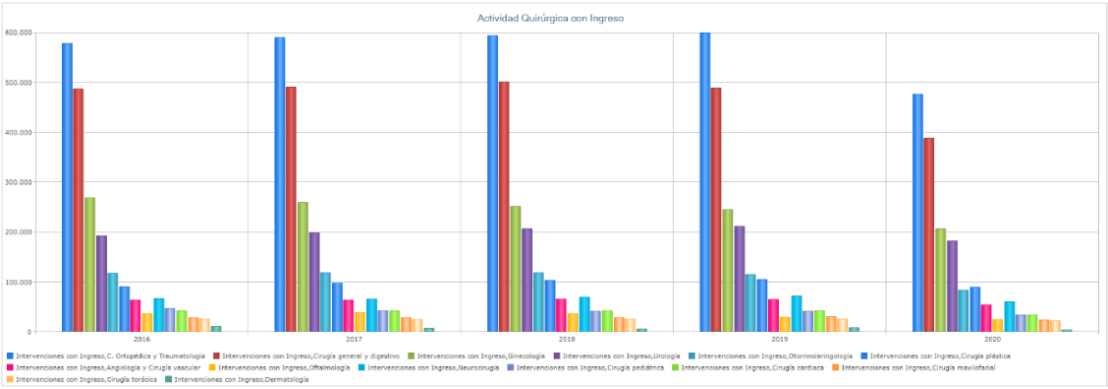
(Statistical portal. Management intelligence area of the Ministry of Health)



Annual relationship of the number of major surgical procedures on the respiratory system.

(Statistical portal. Management intelligence area of the Ministry of Health)

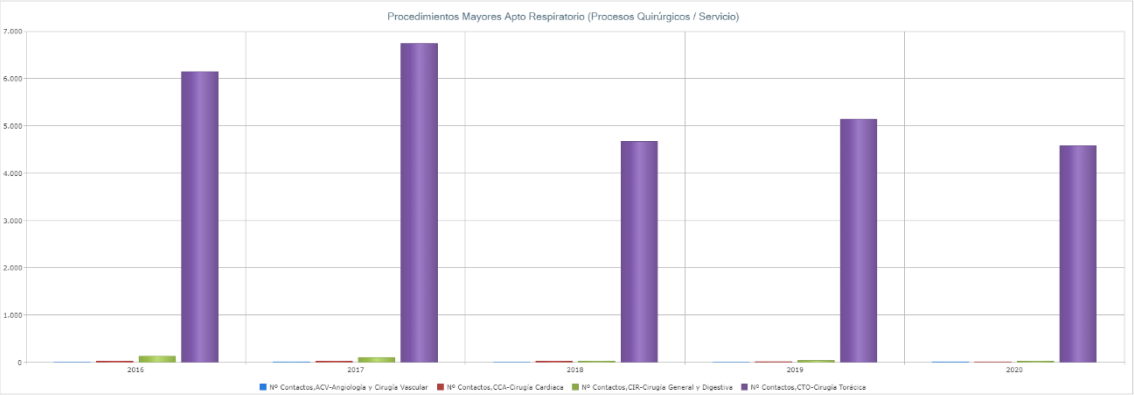
Thoracic surgery represents a small proportion of surgical procedures with hospital admission performed in our country. In fact, according to data from the Ministry of Health itself, our volume with some 25,000 procedures/year represents the second lowest for surgical services, surpassing only the specialty of dermatology (3).



Volume of inpatient surgical procedures by specialties

The fact that it represents a "small" specialty and that almost all thoracic surgical procedures in the adult population in our country are the responsibility of the thoracic surgeon, unlike what happens in other

countries where general, cardiothoracic or cardiovascular surgeons commonly participate in such procedures, places this project in a privileged position to be able to carry out comparative studies with data obtained from administrative records, as they recently did in France from their Epithor registry (4).



Over the last two decades, many predictive models have been developed, mainly in terms of perioperative prognosis, in the field of thoracic surgery. However, the number of works that have tried to validate these models and their updating over the years is scarce. GEVATS was able to develop a predictive model of postoperative morbidity and mortality, internally validated by resampling techniques, after anatomical lung resection, as well as to perform external validation of the main European models, Eurolung 1 and 2 (5)(6).

Despite the work carried out by GEVATS, its cohort, whose recruitment ended more than 4 years ago, will not be adequate to respond in a contemporary way to the value of future regression, classification, and survival models. The significant increase in the availability of data on an ongoing basis will enable ReSECT to develop and validate forecasting tools based on much more powerful computational methods, and with fewer assumptions than traditional statistical methods, with the goal of assisting in decision-making and improving our quality of care.

Finally, ReSECT stands as a dynamic registry that is continuously updated, which will allow us to evaluate the progressive implementation of certain surgical techniques that are on the rise (segmentectomies...), new technologies (robotic surgery platforms...) and future health programs (early detection of lung cancer), as well as the results derived from them for our specialty, professionals and population served.

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2. Hypothesis

The creation of a permanent, inclusive, and dynamic clinical registry promoted by the Spanish Society of Thoracic Surgery will be a turning point in clinical research and healthcare activity of the Spanish thoracic surgery, by being better aware of our clinical practice, our results and our expectations as professionals, institutions, and specialty.

3. Objectives

A. General Objectives

1. Promote a better quality of care in Spanish thoracic surgery.

2. Promote more efficient research through a common platform for the development of future multicenter studies of Spanish thoracic surgery.

3. Collaborate with the professional activity of SECT members by creating a surgical personal registry.

4. Collaborate with other national and international registries of our specialty.

B. Specific Objectives

1. To know the evolution of the main epidemiological and clinical characteristics of patients operated on for thoracic pathology in our country.

2. To evaluate the progressive implementation of new surgical techniques, health technologies or health programs that affect our specialty.

3. To validate perioperative risk models and international oncology prognostic classifications in our environment.

4. To develop and validate our own perioperative and oncological predictive models (overall survival, disease-specific survival, and recurrence-free survival) that allow us to establish quality standards for benchmarking purposes among professionals and institutions in our country.

5. Evaluate and quantify the existence of random effects between institutions on the main perioperative prognostic parameters.

6. To know adherence globally and by institutions to the main clinical practice recommendations in our specialty.

4. Participants

ReSECT is intended for SECT Members including thoracic surgery specialists and residents with professional practice in Spain, as well as thoracic surgery departments in our country.

Participation in ReSECT may be at the individual level (personal surgical registry) and by department (ReSECT surgical processes). Those thoracic surgery departments interested in participating in a surgical process implemented in ReSECT must be represented by a single responsible hospital user. These users will be responsible for:

- To ensure the complete recruitment of patients from her/his institution for those ReSECT surgical processes in which they have expressed their intention to participate voluntarily.
- To communicate the registrations and cancellations of users of his/her institution in due time.
- To export the data of her/his institution and share it with its users.

The complete recruitment of those surgical processes in which each center participates will be a priority. The ReSECT executive committee will recommend to those centers with a constant low level of participation in a certain surgical process, the appointment of a new user as hospital manager, and ultimately the temporary exclusion of his/her center for a period of two years for the surgical procedure in question.

5. Design

ReSECT will be a clinical registry based on surgical procedures. The retrospective/prospective nature of the personal surgical record will be determined by the user's ability to include records of patients who underwent surgery prior to the approval of the current project. However, the "retrospective patients" to be included must belong to the center associated with each user at the time of registering on the platform. In other words, it will not be feasible to include patients operated on in other institutions where the professional had previously worked.

The first ReSECT surgical process of anatomical lung resections, and the successive processes that are to be created in the future, will only contemplate patients operated on prospectively with respect to the date of approval of each surgical process.

A. Personal surgical registry.

Due to the personal nature of this record, a certain surgical procedure in a specific patient may have up to five personal entry records depending on the professional's participation in the procedure (principal surgeon, first assistant, second assistant, third assistant, without participation in the process).

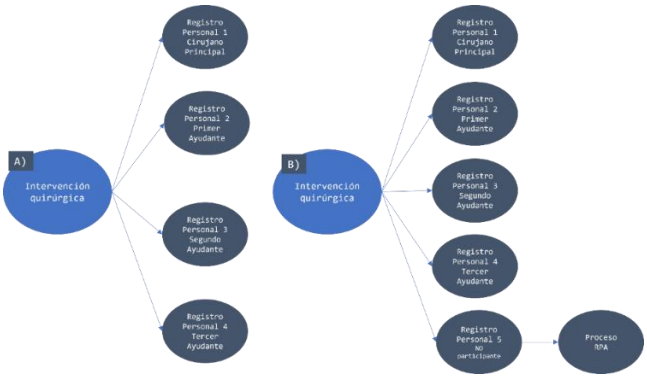
The personal record will be private for the user who creates it, that is, none of the other users will be able to view or modify the personal record data of another colleague.

When a professional leaves a certain institution, the data center, or the scientific director of ReSECT will transfer the pseudonymized data corresponding to their personal records entered during their professional activity in that institution. However, those data will continue to be hosted on the platform on behalf of the institution of origin and under the same conditions that regulate the personal records belonging to the users of each center.

B. Registry of surgical processes by department.

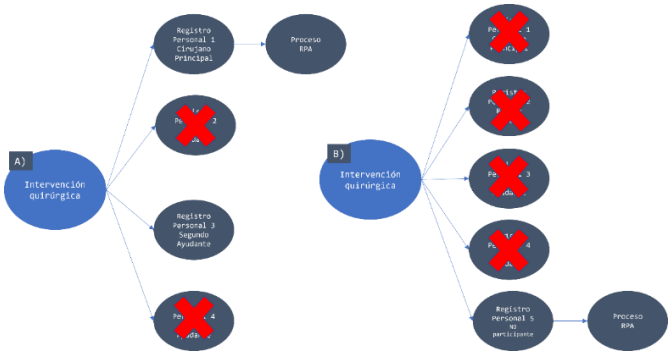
When ReSECT is established, all thoracic surgery departments in Spain will be invited to participate voluntarily in the first ReSECT surgical process of anatomical lung resections. As different surgical processes are implemented, the corresponding invitations will be made, in such a way that a certain department will participate only in those surgical processes that are of interest to it.

Every patient included in a ReSECT surgical process must have been previously included as a personal surgical record by one of the users of each department, whether or not they have participated in the intervention. Thus, it will be the internal decision of each department to determine which user or users must complete the different forms of the patients included in a surgical process. However, for a better quality in data completion, it is recommended that at least the surgical intervention form be completed by one of the surgeons who participated in the procedure. Unlike the personal record, the data within a certain surgical process is visible and editable by all users of each center.



Relationship between Personal Registry and Anatomical Pulmonary Resection Process

The previous figure describes unlikely situations in which: A) All professionals who have participated in an intervention add a personal record, but the procedure is not included in the anatomical lung resection process because the service did not want to participate; B) All professionals who have participated in an intervention add a personal record, but the service has decided that it is a specific professional, who in this case has not participated in the surgical procedure, who includes the data in the process of anatomical lung resections.



Relationship between Personal Registry and Anatomical Pulmonary Resection Process (most likely situations)

The figure above represents the most probable situations of the relationship between the personal surgical record and the anatomical lung resection process: A) Two of the professionals who have participated in the intervention add a personal record, and one of them includes the surgical procedure within the process of anatomical lung resections; B) None of the professionals who have participated in the intervention add a personal record, but the department has decided that it be a certain professional, who in this case has not participated in the surgical procedure, who includes the data in the anatomical lung resection process.

C. Relationship between forms

The ReSECT database at the time it is established will be made up of seven forms: clinical identification data (7 variables), personal surgical record (21 variables in a single form) and anatomical lung resection process (138 variables distributed in 5 forms). The nature and relationship between forms will be defined by:

1. Clinical identification data form: mandatory for all patients in the registry as a prior step to completing a personal registry.
2. Personal surgical record form: at least one personal record is mandatory as a form of access to the different surgical processes. Each personal record will give rise to a procedure identifier that will be a self-calculated composite field that will include the following variables: surgery date – main procedure – procedure subtype (for example: 2022-06-01_Pulmonary_Pneumonectomy). The

variables contained in the personal registration form may be fully completed at the time of hospital discharge.

3. Group of anatomical pulmonary resection process forms: enabled for a specific patient if there is a personal record associated with that patient containing a compatible procedure identifier (yyyy-mm-dd _Pulmonary _ Segmentectomy / lobectomy / bilobectomy / pneumonectomy). The activation of this and future processes is enabled from the clinical data form once a personal record compatible with the surgical process in question has been included.

   Although a certain surgical procedure had been the subject of several personal records, that procedure may only be the subject of a single entry in the process of anatomical lung resections. The relationship between the forms of this process is:

   a. Postoperative form: enabled if the patient did not die during the surgery.
   b. Short-term follow-up form (hospital readmission): enabled if the reason for discharge was other than death.
   c. Long-term follow-up form: enabled if the patient did not die during the first 90 postoperative days and the reason for surgery was a primary malignant lung tumor. Long-term follow-up is recommended for a period of approximately 5 years.

The data will be collected directly through the web platform designed for this project and managed by the digital health company Persei Vivarium. This platform will have an adaptive design for correct viewing and usability on mobile devices, facilitating the completion of data in real time.

In addition, for the same purpose, the information collected in each registration form may be exported to a pseudonymized .pdf file that may be imported as an attachment to the electronic medical record of each patient or simply copy and paste the content of said document in the evolutionary or corresponding clinical report.

6. Patients

A. Inclusion criteria

The inclusion criteria will depend on the section of the registry to be considered.

- Personal record: patients undergoing any type of surgical intervention on the thorax or its border territories.
- Registry of ReSECT Surgical Processes by services: patients undergoing an anatomical pulmonary resection as the first process to be implemented at the time ReSECT was established.

B. Sample size

Taking into account the history of the Spanish Video-assisted Thoracic Surgery Group (3,533 procedures in 15 months of recruitment), the more inclusive nature of the current project, and the number of major lung resections in our country, according to figures from the Ministry of Health (5,000 cases per year), our estimate is that the first surgical process of ReSECT, based on anatomical lung resections, will involve a recruitment of at least 3000 surgical procedures per year.

Although the current project represents the design of a patient registry and not a specific project based on that registry, we have considered of special interest the estimation of the sample size with a view to the development of future predictive models based on one of the perioperative outcomes of greatest interest with a lower incidence (in-hospital death 2%), and therefore maximizing the statistical power with respect to other possible outcomes.

For this calculation, the following parameters were used: proportion of patients who died before discharge from the GEVATS (0.0158), shrinkage factor to control model overfitting (0.9) and Cox Snell Pseudo R2 value (0.032) based on the following model within GEVATS cohort: hospital death ~ age + sex + fev1ppo + dlcoppo + surgical approach + type of pulmonary resection. From these parameters, the necessary sample size was determined based on the number of independent variables to include: 5 variables (1353 patients), 6 variables (1624 patients), 7 variables. (1894 patients), 8 variables (2165 patients), 9 variables (2435 patients), 10 variables (2706 patients).

The calculation was made using the DescTools and pmsampsize libraries for R 4.2.0 software under the R Studio 2022.02.3+492 development environment.

7. Statistical analysis

All the specific studies that are developed from this registry, with specific objectives in line with those previously defined for this project, must have the collaboration, by internal regulations, of a professional in data analysis. That professional must sign as such and appear as co-author of the published work or in the acknowledgments section together with the institution to which he/she belongs or other information that may facilitate his/her professional affiliation.

The periodic scientific reports will include a descriptive analysis globally and disaggregated by department based on the main variables of the registry. Despite the meticulous design of the web tool, mainly through extended validations and filters, the first phase of these reports will include an exploratory analysis in search of implausible values, outliers, and missing values that could influence the results and conclusions that are derived from them.

The categorical variables will be represented based on their absolute and relative frequencies, while for the quantitative variables, measures of central tendency and dispersion will be used in accordance with the distribution of the data. The existence of an association between a variable and a population parameter or between two different variables will be evaluated by hypotheses testing that will be adapted to the nature of each variable (Chi square, Fisher, t-Student, one-factor ANOVA, Mann-Whitney, Kruskal-Wallis). An α error of 0.05 will be accepted in all tests as a common rule. In the event of a statistically significant association involving variables with more than two categories, the corresponding post-hoc contrasts will be performed using adjustment techniques (Tukey, Bonferroni). The size of the effect between variables will be evaluated using the most widely accepted estimators (r-Pearson, Spearman's rho, Kendall's tau, Cohen's d and v'Cramer).

The degree of association between dependent and independent variables will be determined using regression techniques (binary, multinomial, Poisson, Cox) reporting the effect size in terms of Odds Ratios or Hazard Ratios, as appropriate, with 95% confidence intervals. In addition to the classic regression models, new classification algorithms will be implemented, mainly based on supervised machine learning techniques (random forests and support vector machines).

The validation of external predictive models will include goodness-of-fit techniques to assess the model's calibration and discrimination techniques, mainly based on the area under the ROC curve and the concordance index for non-binary dependent variables. In the case of models with a good degree of discrimination, their recalibration for use in our environment will be assessed. The accuracy of the predictions will be evaluated using specific estimators for each type of model. The internal validation of the models built from the registry data will be carried out using resampling or cross-validation techniques. The performance between institutions will be made for those outcomes that act as dependent variables of previously validated models. The effect of a given type of treatment on a dependent variable will be determined using propensity score techniques adapted to current European recommendations.

The periodic scientific reports by the main investigator of this project will be carried out using the R software, with RStudio as the development environment and the help of the following libraries according to their main functions: data cleaning (Tidyverse), exploratory analysis (DataExplorer and MICE), descriptive analysis (Summarytools, CompareGroups, Finalfit), visualization (GGplot2 and Plotly) and modeling (Tidymodels, Caret, Mlr3). The development of interactive web applications will be carried out using the reactive programming system Shiny for R.

All the research works derived from the current ReSECT project will be adapted to the current internationally established recommendations for transparency in publication.

8. Audit

One of the main priorities of the current registry will focus on obtaining quality data that are representative of the registry's target population.

A. In data collection.

The first phase of quality control will be related to the moment of data collection and will be determined by:

- Registry design: restrictions and warnings to avoid unlikely or inconsistent values between two or more variables; extended validations to avoid input errors.
- Web tool: filters and descriptive statistics available to the user within the platform itself. These options allow, for example, the user to know the percentage of missing values in those variables that they are interested in knowing directly from the platform or once the filtered data has been exported.
- Periodic scientific reports prepared by the scientific director: a section of these reports will be devoted to evaluating the percentage of missing values in certain variables in each department.

B. Internal audit systems

- Annual reports issued by the person in charge of the clinical documentation service of each participating center and addressed to the ReSECT executive committee. These reports must reflect the number of candidate procedures to be part of a certain ReSECT process in each calendar year, allowing the recruitment percentage of each center to be known.
- Audit of variables or sets of variables considered key due to their scientific interest, or due to the possibility of entailing conflicts of interest for the participating professionals or institutions. This audit step may be carried out based on pseudonymized registration reports sent to the general secretary of ReSECT and/or through videoconferences under a secure environment established by the management of the center to be audited.

9. Limitations

Due to the voluntary nature of the current registry, its main limitation will be determined by the representativeness of the study population, which in turn will depend on the number and type of participating institutions, and the recruitment percentage of each of them. The compromise of representativeness could suppose the introduction of systematic biases that jeopardize the external validity or generalization of our results, and therefore the possibility of exporting our findings to other scenarios.

Another of the limitations that the current registry must face is the information bias resulting from the inclusion of untrue data, intentionally or not. Such limitation may compromise, especially, certain variables whose real values may suppose a conflict of interest with the professionals or institutions that participate. Sharing the same reasoning, selection bias would mean that the inclusion of patients could be conditioned by their baseline characteristics, with individuals with a more favourable clinical profile being more likely to be invited to participate in the registry, or preferentially recruiting those patients who have presented a more beneficial postoperative course or have undergone surgical techniques of special interest.

The observational nature of this registry also jeopardizes the internal validity of our results because of the confusion bias by indication (channeling bias), consisting of the tendency of professionals to indicate certain drugs, or type of surgical procedure in our case, based on the prognosis of a given patient. For example, sublobar vs. lobar resection, VATS approach vs. thoracotomy, and VATS approach vs. robotic surgery, among others.

Finally, and also secondary to the observational nature of the study, certain potential confounding factors not included in our study, intentionally for reasons of practicality given the high probability of missing values or as a consequence of a not favourable effort-benefit balance in their collection, and unintentionally, in case of non-quantifiable variables, they could compromise the size of the effect associated with certain risk factors and/or types of treatment, or the external validity of some of the predictive models derived from our cohort.

The audit systems established by the current registry, and described in the procedures section of this protocol, are intended to overcome these potential limitations in terms of internal and external validity before the start-up of this registry. We believe that the a priori knowledge of these audit systems will have a positive impact on the quality of the data collected. On the other hand, the mandatory active collaboration of a professional in data analysis in all research projects derived from the current registry, will favour to minimize the impact of such limitations and, in any case, improve the interpretation of our results under such conditions.

10. Regulation

The executive committee of ReSECT will be the part responsible for making decisions that affect the objectives, regulation, and structure of ReSECT. This committee is constituted as a semi-permanent commission made up of a scientific director, institutional coordinator, and general secretary.

In addition to the executive committee, the structure of ReSECT is defined by a triennial scientific committee made up of five thoracic surgeons with professional practice in the national territory and number members of the Spanish Society of Thoracic Surgery. The election of the members of the scientific committee will be

the responsibility of the executive committee, except in the case of the representative of the Board of Directors of SECT in that committee.

11. Patient privacy

On the ReSECT platform, each professional, through a username and password, will only have access to the information of the patients who underwent surgery in their institution. The patients registered by each user will be identified on the platform by the “hospital of origin” and a “representative code”. Such code will be generated by means of a logical rule and/or linear combination applied to a certain identification document. Both the rule to be applied and the document from which that code is generated will be agreed and confidential between the professionals of each service. No other direct identification data such as name, surname or personal documents will be collected.

The only user with the capacity to export all the data from the platform will be the scientific director of ReSECT, who will be responsible for the transfer of pseudonymized data to those users who have proposed specific internal research projects based on the registry data and have the approval of the executive and scientific committee of ReSECT. Therefore, the transfer of clinical data for the purpose of those projects will be carried out without the end user being able to associate any clinical data with a specific patient.

The data transfer process will be carried out through the export seed of the web platform itself, managed by the specialized digital health company Persei Vivarium (CIF-B87263885. c/ Gran Vía 62, 28013 Madrid).

12. Ethics committee approval

GOBIERNO DE ARAGON
Departamento de Sanidad

Favorable Opinion Report
C.P – C.I PI22/367 7
September 2022

Ms. María González Hinjos, Secretary of CEIC Aragón (CEICA)

CERTIFIES

1st. That the CEIC Aragón (CEICA) at its meeting on 09/07/2022, Act No. 15/2022, has evaluated the proposal of the researcher referred to the study:

Title: Registry of the Spanish Society of Thoracic Surgery (ReSECT)

Principal Investigator: Raul Embún Flor, HU Miguel Servet

Protocol version: Version 1.1 (08/10/2022)

Information and consent document version: Version 1.1 (08/10/2022)

2nd. Consider that

- The project is proposed following the requirements of Law 14/2007, on biomedical research and its implementation is relevant.

- The necessary requirements of suitability of the protocol in relation to the objectives of the study are met and are justified risks and foreseeable inconveniences for the subject.

- The use of data and documents prepared to obtain consent is appropriate.

- The exemption of informed consent is allowed to collect the requested data only in those cases in which the patient is not going to return to the consultation, either due to death or another reason.

- The scope of the financial compensation provided does not interfere with respect for ethical principles.

- The capacity of the investigators and the means available are appropriate to carry out the study.

3rd. Therefore, this CEIC issues a **FAVORABLE OPINION to carry out the study.**

GONZALEZ HINJOS MARIA - DNI 03857456B
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María González Hinjos
Secretaria del CEIC Aragón (CEICA)

13. Information document for the participant

Project title: **REGISTRO DE LA SOCIEDAD ESPAÑOLA DE CIRUGÍA TORÁCICA**

Promotor: **SOCIEDAD ESPAÑOLA DE CIRUGÍA TORÁCICA**

Principal Investigator:

Institution

1. Introduction:

We are writing to you to request your participation in a research project that we are carrying out at the hospital……. Your participation is completely voluntary, in no case should you feel obligated to participate, but it is important to obtain the knowledge we need. This project has been approved by an Ethics Committee. Before making a decision, it is necessary that:

- Read this entire document.

- Understand the information contained in the document.

- Ask all the questions you consider necessary.

- Make a thoughtful decision.

- Sign the informed consent, if you finally want to participate.

If you decide to participate, you will be given a copy of this sheet and the signed consent document. Please keep it in case you need it in the future.

2. Why are you being asked to participate?

Your collaboration is requested because you are scheduled to undergo a surgical procedure on the thorax or one of its border regions. The study consists of a permanent record of the national surgical activity of our specialty, which is why it is being carried out in most of the Thoracic Surgery Services in the country.

3. What is the object of this study?

The objective of this study is to know the clinical care practice of our specialty and thus be able to obtain quality clinical data that allow us to improve the care we offer our patients. In addition, this study intends to collaborate in the future with the registry of the European Society of Thoracic Surgery through the transfer of data to it.

4. What do I have to do if I decide to participate?

Participating in this study only implies accepting that your clinical data will be included in a health data platform managed by a company specialized in digital health (Persei vivarium).

5. What risks or inconveniences does it entail?

By participating in the study you will not undergo any additional type of invasive or non-invasive intervention, nor does it require you to attend more medical visits than you should already attend according to the protocols of the hospital where you are being treated.

6. Will I get any benefit from my participation?

You will not receive any benefits from taking part in this study, nor are you likely to receive benefits in the future.

7. How will my personal data be treated?

The data that will be collected about your health has to do with your previous illnesses and the type of tests that have been carried out before the operation (anthropometric data, imaging tests, respiratory function study...), the type of surgery that will be performed (surgical approach, type of anaesthesia, duration of surgery, type of procedure...), the postoperative course in the hospital after the surgical intervention (type of care, complications, days of hospital stay...) and the evolution of your state of health once you are discharged from the hospital (hospital readmission, disease control, follow-up time...).

The data will be processed by a company specialized in digital health (Persei Vivarium). The person in charge of this study at the hospital where you are being treated will be Dr……., who will be at your complete disposal to clarify any doubts that may arise in relation to your collaboration.

Purpose: Your personal data will be treated exclusively for the research work referred to in this document.

Legitimation: The treatment of the data of this study is legitimized by your consent to participate.

Recipients: Your clinical data may always be transferred anonymously to other health registries with similar characteristics and objectives to those of this national registry.

Rights: You can exercise your rights of access, rectification, deletion and portability of your data, of limitation and opposition to its treatment, in accordance with the provisions of LO 3/2018 on Protection of Personal Data and guarantee of digital rights and the General Data Protection Regulation (RGPD 2016/679) before the main investigator of the project, being able to obtain information in this regard by sending an email to the address dpd@salud.aragon.es. If you wish to withdraw from the study, you can request the deletion of your data.

You can consult additional and detailed information in the Registry of Processing Activities of the Government of Aragon, at the following link:
https://aplicaciones.aragon.es/notif_lopd_pub/details.action?fileId=731

Likewise, in compliance with the provisions of the RGPD, it is reported that, if you wish, you can go to the Data Protection Agency (https://www.aepd.es) to file a claim when you consider that it is not have duly respected your rights.

The processing of your personal data will be carried out using techniques to maintain your anonymity using random codes, so that your personal identity is completely hidden during the investigation process.

Based on the results of the research work, scientific communications may be prepared to be presented at congresses or scientific journals, but they will always be done with grouped data and nothing that can identify you will ever be disclosed.

You can consult the privacy policy of the specialized company that will manage your health data at https://perseivivarium.com/privacy.php

9. Who finances the study?

This project is financed with funds from the Foundation of the Spanish Society of Thoracic Surgery. The knowledge derived from this study is not intended to generate commercial benefits.

10. Will I be informed of the results of the study?

You have the right to know the results of this study, both the general results and those derived from your specific data. You also have the right not to know such results if you wish. For this reason, in the informed consent document we will ask you which option you prefer. In case you want to know the results, the investigator will send you these results.

Sometimes when carrying out a research project, unexpected findings are found that may be relevant to the health of the participant. In the event that this occurs, we will contact you so that you can see your regular doctor.

Can I change my mind?

Your participation is completely voluntary, you can decide not to participate or withdraw from the study at any time without having to give reasons and without this affecting your health care. You just need to tell the principal investigator of the study your intention. In case you decide to withdraw from the study you can request the destruction of the data, samples or other information collected about you.

What happens if I have any questions during my participation?

The first page of this document contains the name and contact telephone number of the investigator responsible for the study. You can contact him if you have any questions about your participation. You can also contact the person in charge of the study at your hospital of origin: Dr …….

Thank you very much for your attention, if you finally wish to participate, please sign the attached consent document and we reiterate our gratitude for contributing to generating scientific knowledge.

INFORMED CONSENT DOCUMENT

Project title: REGISTRO DE LA SOCIEDAD ESPAÑOLA DE CIRUGÍA TORÁCICA (ReSECT)

I, ... I have read the information sheet given to me.

I have been able to ask questions about the study and have received enough information about the study.

I have spoken with: .....(name of investigator)

I understand that my participation is voluntary. I understand that I can withdraw from the study:

1) whenever you want

2) without having to explain

3) without this affecting my medical care

I freely give my consent to participate in this study and I give my consent for the access and use of my data as stipulated in the information sheet that has been given to me.

I wish to be informed about the results of the study: Yes ☐ No ☐ (check as appropriate)

I give my consent for my clinical data to be reviewed by personnel outside the center, for the purposes of the study, and I am aware that this consent is revocable.

I have received a signed copy of this Informed Consent.

Participant signature: ……. **Date**:

Mr. / Ms…….. with ID……. I declare that the doctor,

Dr/Dra....., has explained to me what the current study consists of and therefore I give my consent for the patient Mr./Mrs… …… with ID……... to participate in the study.

Signature of the legal representative …… **Date:**

I have explained the nature and purpose of the study to the named patient

Investigator signature: …… **Date**: