

VERIFICATION REPORT

Organization:	Instituto Valenciano de Infertilidad (IVI)		
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Organization Representatives:	José Gregorio Iniesta Mª José de los Santos		
Verification dates:	22-23/03/2016	Verification locations:	C/ Luis Buñuel director de cine 1, puerta 5 C/ Plaza Policía Local, 3 46015 Valencia
Head Verifier:	Reyes Salinas	Other members of the verifying team:	-
Version v01 invalidates and replaces version v00			

SCOPE

SGS Tecnos, S.A. (hereinafter SGS) has performed, at request of the Instituto Valenciano de Infertilidad (hereinafter IVI), the independent verification of the document named “Clinical results 2015.ppt”

The verification’s scope includes the text and data contained in the above mentioned reference document.

Said data matches the results of all the clinics from the IVI group, both national and international (in Europe, Latin America and Abu Dhabi) and refer to treatments performed during the time period comprised between 01/01/2015 and 31/12/2015.

For those results presented in the document “Clinical results 2015.ppt” in which the study includes an historical period of data outside 2015 or refers only to data from some of the clinics, the considered period will be specifically detailed as well as the clinics where the study was performed.

INDEPENDENCE

The information contained in the verified document and its elaboration is the responsibility of IVI.

SGS has not participated nor counselled in the elaboration of the verified document, restricting itself to act as an independent verifier by checking the validity of its contents.

The contents of this Verification Report and the opinions therein contained are the sole responsibility of SGS.

VERIFICATION

Methodology and verification team

The verification methodology applied, established by SGS, is based on verification procedures according to the ISO 19011 norm and on verification mechanisms according to assurance guides and based in relevance, exhaustiveness and response capability principles. Among the methodology used to verify the information and data are:

- Interviews with the personnel responsible for the gathering and preparation and the data.
- The revision of documents and records (both internal and public).
- The checking of data and the validation of the same directly at the sources.
- The verification of the corrections and modifications proposed that were added to the final document.

In particular, for the verification of clinical data, the information evaluated originated from the specific databases that store the clinical results from protocols and patients.

These are:

- Servoy: used in national clinics, Lisbon, Buenos Aires, Chile, Panama and Abu Dhabi (SIVIS).
- Filemaker: used in some clinics in Latin America (Mexico, Salvador and Sao Paulo).

The data verification was performed by means of visits to IVI Valencia on 22 and 23/03/2016 (Systems Department and IVI3 Clinic).

The verification team was formed by personnel from SGS

- Ms Reyes Salinas González (Verifier)

and was set up according to her knowledge, experience and qualifications for the performance of this independent verification.

Verification development

Using the document "Clinical results 2015.ppt" as base, the origin of the data was verified, as well as the extraction, transformation, loading and calculation of all the values presented in the report.

The clinical results from the 2015 memory correspond to the loading of data performed on 02/03/2016.

The systematics followed by the IVI personnel for the inclusion of the data in Servoy has been verified, including:

- Data registry in paper form in the laboratories of different clinics (Valencia, Bilbao, Sevilla, Alicante).
- The uploading of said data into the SIVIS database.

- Verification on the embryologists part of the data included in the database before the definitive filing of the paper forms containing the original registry.

During the visit to the Valencia IVI clinic, the team verified the correct storage of data in SIVIS, checking several clinical chart numbers (NHC) and protocols in paper forms corresponding to several treatments (ICSI, FIV, Egg Donation, Vitrification, PGD FISH, PCR, IAD, IAH, etc.) both in patients from the Valencia clinic and in patients from other IVI clinics (through the consultation of paper forms duly scanned and encrypted).

The corroborated data for each protocol correspond to the variables necessary for the retrieval of the different indicators in the clinical results (number of embryos transferred, BhCG test results, ultrasound scan results, number of sacs seen in scan, chemical miscarriages, clinical miscarriages... as well as the clinical gynecological history of the patients that include the specialists' comments).

The use given to all data was also verified, as well as the consultations defined with Data Transformation Services (DTS), the use of SQL to obtain the results presented in the 2015 memory and the definition and execution of cubes (through SQL repository tools), from which the several variables that are part of the clinical results were obtained.

Throughout the visit the calculation formulae from the different indicators presented as graphics were also verified.

CONCLUSIONS

Based on the executed verification, the verifying team of SGS considers that:

- The document named "Clinical results 2015.ppt" from IVI contains trustworthy data and information and has been elaborated according to the relevance, exhaustiveness and response capability principles.
- These results represent in a coherent way the clinical results of the organization for the aforementioned period.

Valencia, March 31st 2016

Signed
Head Verifier Jefe



Reyes Salinas González