

VERIFICATION REPORT			
Organization:	Instituto Valenciano de Infertilidad (IVI)		
Address:	C/ Góngora, 1 1ª – 46025 (Valencia)		
Organization Representatives:	José Gregorio Iniesta Mª José de los Santos		
Verification dates:	10/05/2017	Verification locations:	C/ Luis Buñuel director de cine 1, puerta 5 C/ Plaza Policía Local, 3 46015 Valencia
Head Verifier:	Reyes Salinas	Other member of the verifying team:	-
Version v01 invalidates and replaces version v00			

SCOPE

SGS Tecnos, S.A. (hereinafter referred to as “SGS”) has performed, at the request of the Instituto Valenciano de Infertilidad (hereinafter referred to as “IVI”), the independent verification of the document entitled “Clinical results 2016.ppt”

The scope of verification includes the text and data contained in the above-mentioned reference document.

Such data matches the results obtained from all clinics within the IVI group, both national and international (in Europe, Latin America and Abu Dhabi) and refer to the treatments performed during the time period comprised between 01/01/2016 and 31/12/2016.

For those results presented in the document “Clinical results 2016.ppt” in which the study includes a history data excluding 2016 or refers only to data obtained from some of the clinics, the specific period and the clinics where the study was performed have been specifically detailed.

INDEPENDENCE

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

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

The content 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 standard and on mechanisms for verification of compliance and based in relevance, exhaustiveness and response capability principles. Among the methodology used to verify the information and data we find:

- Interviews with the personnel responsible for the collection and preparation of data.
- The review of documents and records (both internal and public).
- The verification of data and the validation of the same directly from the sources.
- The verification of the proposed corrections and amendments that were incorporated to the final document.

In particular, for the verification of clinical data, the information evaluated was extracted from the specific databases that store the clinical results from protocols and patients, and which include:

- Sivis: used in national (Spanish) clinics, Lisbon, Buenos Aires, Chile, Panama and Abu Dhabi.
- Filemaker: used in some clinics in Latin America (Salvador).

The data verification was performed by means of visits to IVI Valencia on 10/05/2017 (Systems Department and the 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

Focusing on the “Clinical results 2016.ppt”, the origin of the data was verified, as well as the extraction, transformation, loading and calculation of all those values included in the report.

The clinical results from the 2016 annual report refer to the loading of data from 02/05/2017.

The systematics followed by the IVI personnel for the inclusion of the data in SIVIS has been verified, and includes the following:

- Data registry in the IVF laboratories of different clinics
- The uploading of said data into the SIVIS database.
- Verification made by the embryologists concerning the data included in the database.

During the visit to the IVI Valencia clinic, the team verified the correct storage of data in SIVIS, checking several clinical history numbers (CHN) and protocols corresponding to several treatments (ICSI, IVF, Egg Donation, Vitrification, PGD FISH, PCR, IUI with donor sperm, IUI with partner sperm, etc.) both in patients from the Valencia clinic and in patients from other IVI clinics.

The verified data for each protocol correspond to the variables necessary for the analysis of the different indicators in the clinical results (number of embryos transferred, BhCG test results, ultrasound scan results, number of sacs seen in scan, biochemical 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 2016 annual report and the definition and processing of cubes (through SQL repository tools), from which the different variables that are part of the clinical results were obtained.

During 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 entitled "Clinical results 2016.ppt" from IVI contains trustworthy data and information and has been elaborated according to the relevance, exhaustiveness and response capability principles.
- These results present in a coherent way the clinical results of the organization for the aforementioned period.

Valencia, May 18th, 2017

Signed by:
Head Verifier

Reyes Salinas González