

CLINICAL RESULTS 2017.





VERIFICATION REPORT



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VERIFICATION REPORT

Organization:	Instituto Valenciano de Infertilidad (IVI)		
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Organization Representatives:	Carlos Noguera José Gregorio Iniesta MP José de los Santos		
Verification dates:	29/05/2018	Verification locations:	C/ Colón, 1 46004 Valencia C/ Plaza Policía Local, 3 46015 Valencia
Head Verifier:	Begoña Valero Ciscar	Other member of the verifying team:	-

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 2017.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 (Chile, Buenos Aires, Panamá, Salvador de Bahía, and Mexico), Rome and Abu Dhabi) and refer to the treatments performed during the time period comprised between 01/01/2017 and 31/12/2017.

For those results presented in the document "Clinical results 2017.ppt" in which the study includes a history data excluding 2017 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.



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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, Rome, Buenos Aires, Chile, Panamá, Mexico and Abu Dhabi.
- Filemaker: used in some clinics in Salvador de Bahía, however they are currently undergoing transition to the SIVIS system.

The data verification was performed by means of visits to IVI Valencia on 29/05/2018 and (IT Department and the Clinic).

The verification team was formed by personnel from SGS:

- D^a. Begoña Valero Ciscar (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 2017.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 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 in paper form



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corresponding to several treatments (ICSI, IVF, Egg Donation, Vitrification, PCR, 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 2017 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.

CONCLUSIONS

Based on the executed verification, the verifying team of SGS considers that: The document entitled "Clinical results 2017.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, the 6th of June of 2018

MARIA
BEGOÑA
VALERO
CISCAR

Digitally signed by
MARIA BEGOÑA
VALERO CISCAR
Date: 2018.06.21
16:18:09 +02'00'

Signed,
Begoña Valero Ciscar
Verifier



RESULTS OF ASSISTED REPRODUCTION TREATMENTS PERFORMED AT IVI GROUP IN 2017.

In Vitro Fertilisation (IVF-ICSI)	14.648 cycles
Egg donation (OVODON)	7.561 cycles
Pre-Implantation Genetic Diagnosis (PGD)	7.994 cycles
Artificial insemination (AI)	3.580 cycles
<hr/>	
Transfer of cryopreserved embryos	16.129 treatments
Vitrification of ova	4.277 treatments
<hr/>	
Total	54.189 treatments

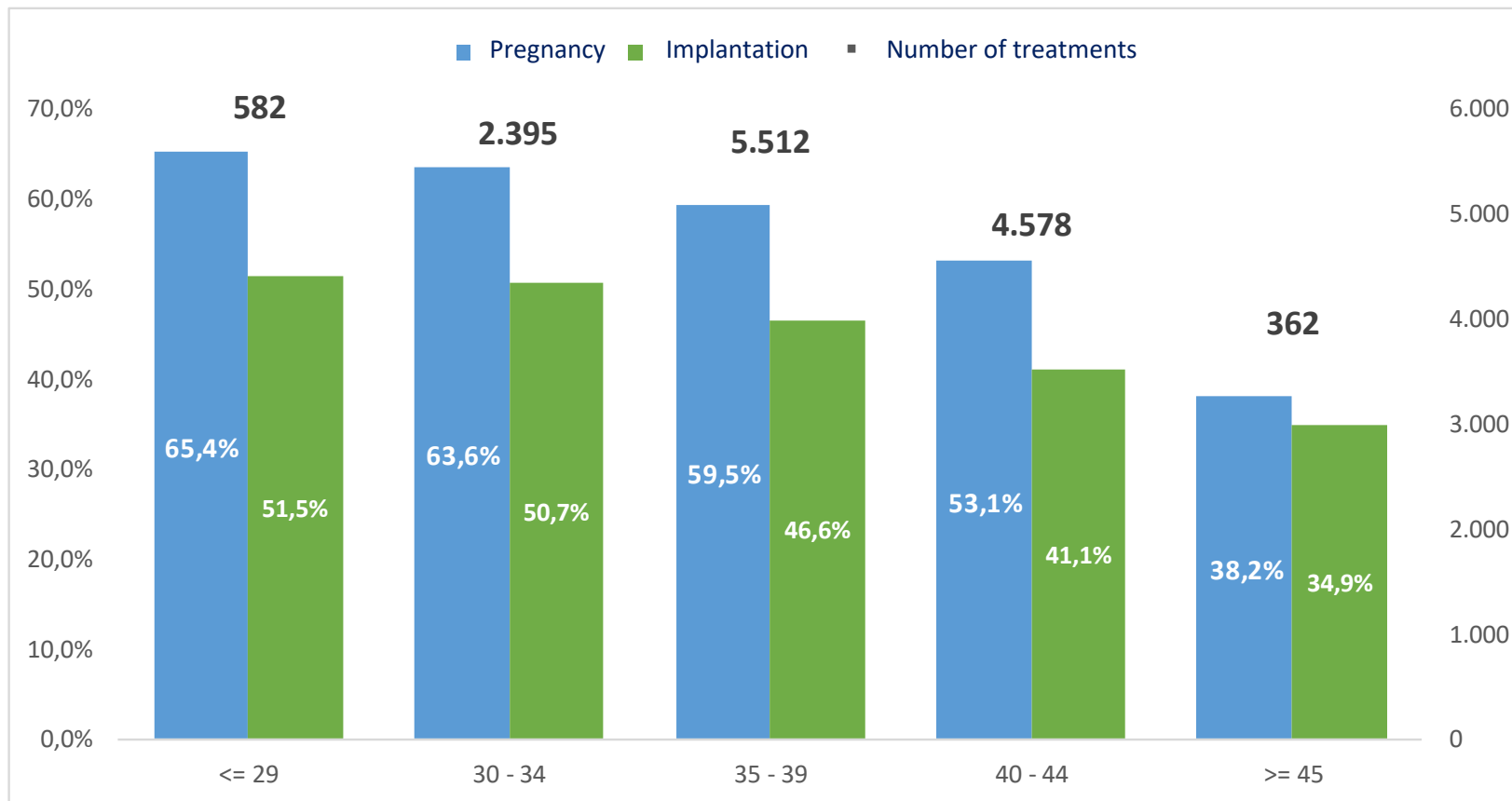
NOTE: Number of procedures in our clinics in Spain + Lisbon + Latin America (Chile, Buenos Aires, Panama, Salvador de Bahía, Mexico) + Rome + Abu Dhabi.



IVF-ICSI AND OVODÓN RESULTS 2017.

	IVF - ICSI	OVODON
Cycles performed (Cycle transfers)	14.648 (3.529)	7.561(5.684)
No. pregnancies	1.938	3.909
% pregnancy per transfer	54,9	68,8
% implantation per embryo transferred	40,0	56,7
% twin pregnancy	15,0	13,6

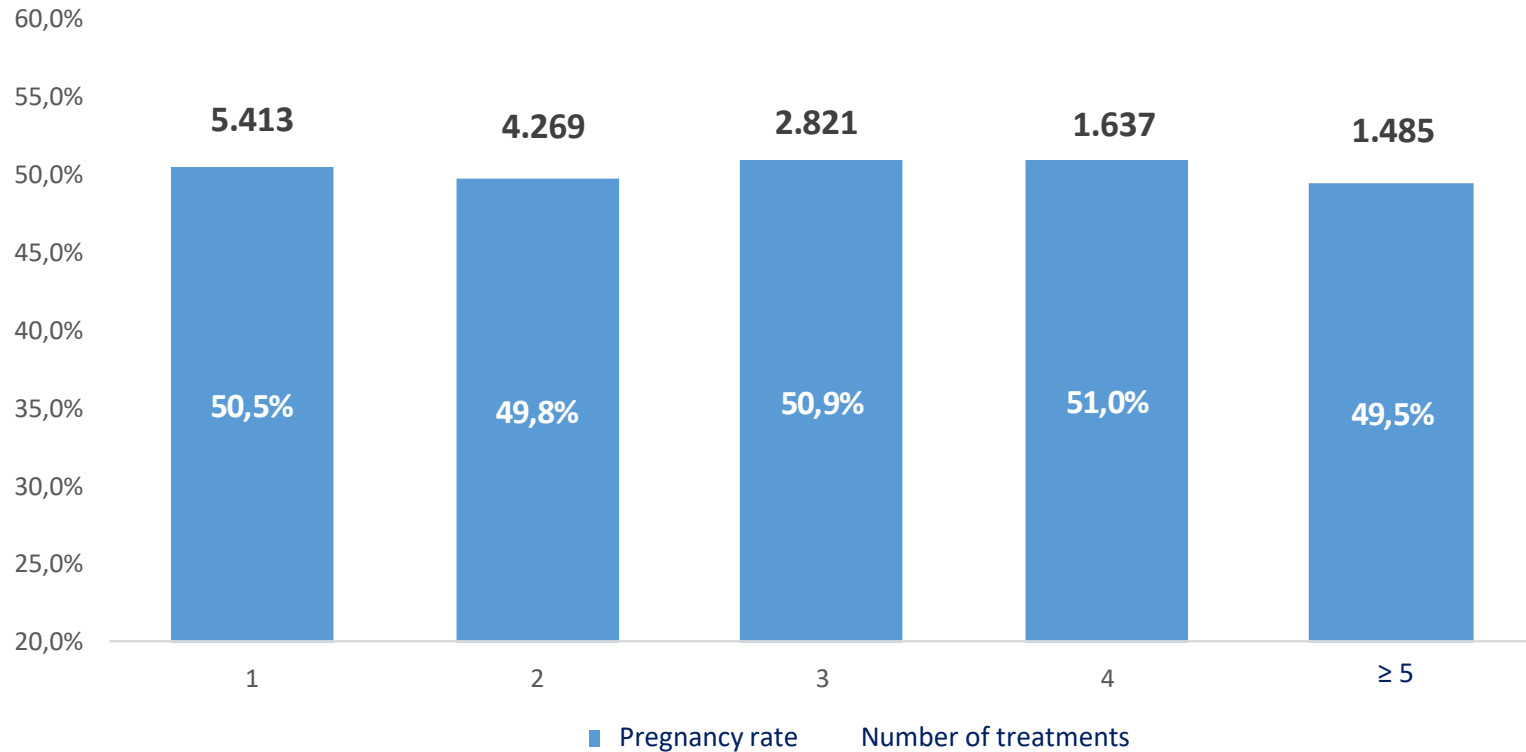
NOTE: Number of procedures in our clinics in Spain + Lisbon + Latin America (Chile, Buenos Aires, Panama, Salvador de Bahía, Mexico) + Rome + Abu Dhabi.



NOTE: This rate includes the rates of fresh transfers and those deferred from them (transfers of cryopreserved embryos from the fresh procedure). For the clinics in Spain + Lisbon + Chile + Panama + Buenos Aires + Mexico + Rome + Abu Dhabi.



PREGNANCY RATE IN A FIRST IVF-ICSI ATTEMPT AT AN IVI CENTER, ACCORDING TO THE NUMBER OF PREVIOUS ATTEMPTS AT OTHER CENTRES.



NOTE: The graph shows the figures of treatments for patients with previous cycles, including transfers of cryopreserved embryos, between 2007 and 2017 at our clinics in Spain + Lisbon + Rome.



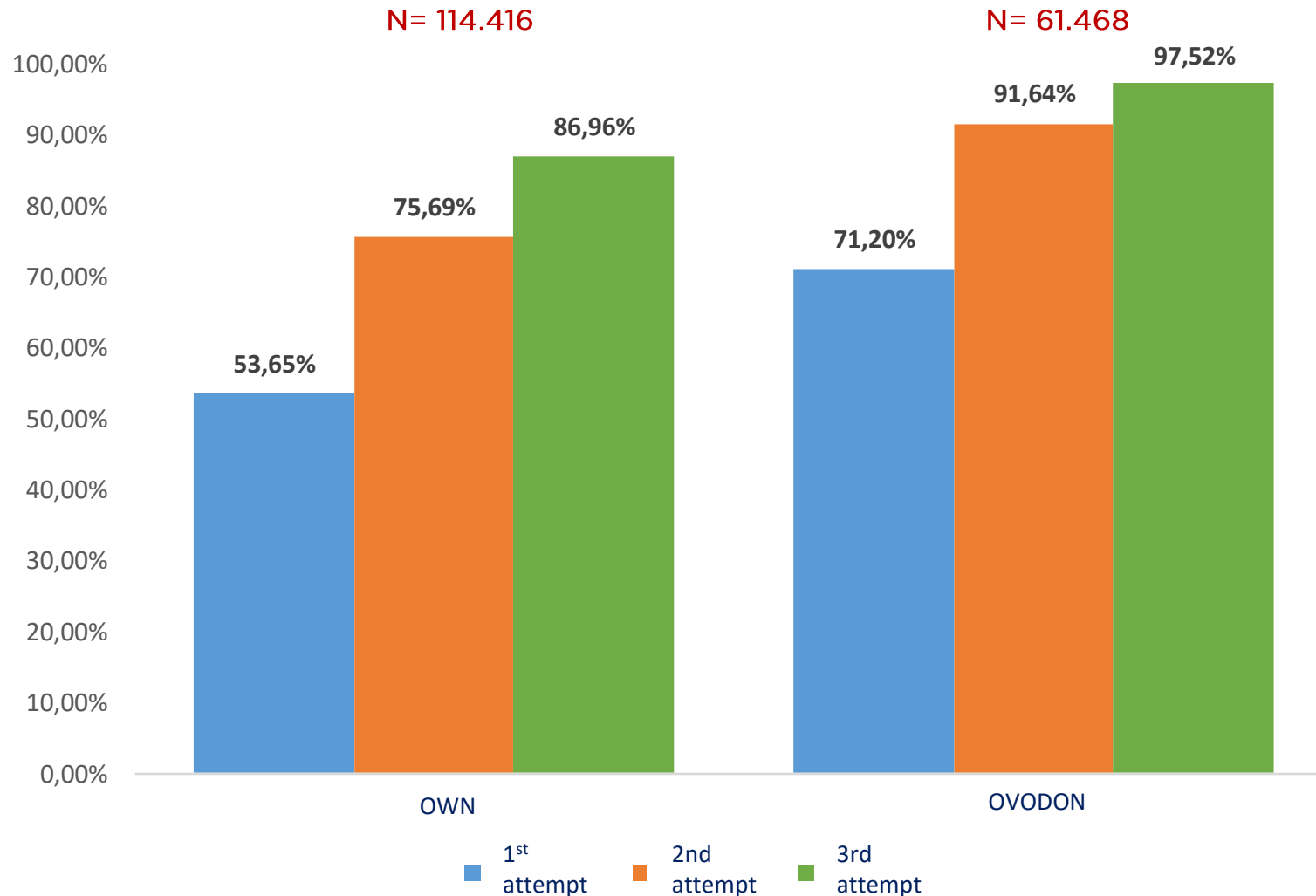
TRANSFER OF CRYOPRESERVED EMBRYOS RESULTS 2017.

	TOTAL
Thawing (Transfers of cryopreserved embryos)	16.129(15.442)
Embryo transfer rate %	95,7
No. of pregnancies	8.672
% Pregnancy per transfer	56,2
% Embryo implantation	44,2

NOTE: Number of procedures in our clinics in Spain + Lisbon + Latin America (Chile, Buenos Aires, Panama, Salvador de Bahía, Mexico) + Rome + Abu Dhabi.



ACCUMULATED RATE OF CLINICAL PREGNANCY AFTER THREE ATTEMPTS. (includes transfer of cryopreserved embryos)



NOTE: The graph shows the rate in our clinics in Spain + Lisbon + Latin America (Chile, Buenos Aires, Panama, Salvador de Bahía, Mexico) + Rome + Abu Dhabi.



	TOTAL
Cycles performed (Transfers)	5.885 (4.105)
% Abnormal embryos	59,0%
No. of pregnancies	2.619
% Pregnancy per transfer	63,8%
% Implantation	55,5%

NOTE: Results of patients with procedures using biopsied embryos at our clinics in Spain + Lisbon + Latin America (Chile, Buenos Aires, Panama, Mexico) + Rome + Abu Dhabi.

Myotonic Dystrophy, Fragile X Syndrome, Cystic Fibrosis, Spinal Muscular Atrophy	
Cycles performed (Transfers)	239(235)
No. of pregnancies	132
% Pregnancy per transfer	56,2%
% Implantation	44,0%

NOTE: Results of patients with procedures using biopsied embryos at our clinics in Spain + Lisbon + Latin America (Chile, Buenos Aires, Panama, Mexico) + Rome + Abu Dhabi.



Treatment	Artificial Insemination (with donor semen)	Artificial Insemination
Nº Cycles	1.726	1.854
Pregnancies	442	298
% pregnancy/Cycle	25,6%	16,1%
% twin pregnancy	8,4%	10,8%

NOTE: Number of procedures in our clinics in Spain + Lisbon + Latin America (Chile, Buenos Aires, Panama, Salvador de Bahía, Mexico) + Rome + Abu Dhabi.



RATIOS NEW BORN BABIES (NBB)

OWN

	AGE	OWN FRESH	OWN CRYOPRESERVED	OWN FRESH + CRYOPRESERVED
NBB PER CYCLE	< 35	43,0%	64,2%	48,8%
	35 - 37	32,0%	31,3%	31,8%
	38 - 40	19,0%	25,5%	20,7%
	40 - 42	8,5%	20,6%	10,9%
	> 42	2,3%	17,5%	4,7%
NBB PER EMBRYO TRANSFERRED	< 35	28,7%	43,8%	32,7%
	35 - 37	23,1%	22,4%	22,9%
	38 - 40	17,0%	19,4%	17,7%
	40 - 42	13,1%	17,8%	14,5%
	> 42	7,0%	17,7%	10,9%
PROPORTION OF SINGLE NBB	< 35	70,0%	79,3%	72,4%
	35 - 37	77,0%	84,7%	79,3%
	38 - 40	85,3%	87,8%	86,1%
	40 - 42	89,8%	91,0%	90,3%
	> 42	91,8%	90,1%	91,2%

OVODON

	OVODON FRESH	OVODON CRYOPRESERVED	OVODON FRESH + CRYOPRESERVED
NBB PER CYCLE	46,4%	31,5%	41,3%
NBB PER EMBRYO TRANSFERRED	29,1%	22,2%	26,9%
PROPORTION OF SINGLE NBB	72,8%	82,4%	75,5%

NOTE: The information represents the ratios of newborn babies from treatments in our clinics in Spain + Lisbon. Period from 2003 to 2016.



- Cycles:** Every complete attempt from stimulation to transfer of fresh or frozen embryos, or the insemination of the qualified ejaculate, which the patient makes.
- Treatment:** Partial procedures that are part of the patient's Assisted Reproduction cycle (e.g. frozen embryo transfers, freezing semen or vitrification of oocytes).
- Pregnancy rate:** percentage of positive pregnancy biochemical test results in relation to the number of embryo transfers.
- Clinical pregnancy rate:** percentage of pregnancies with gestational sac observed on ultrasound in relation to the number of embryo transfers.
- Implantation rate:** percentage of gestational sacs observed on ultrasound in relation to the number of embryos transferred.
- Twin pregnancy rate:** percentage of clinical pregnancies with 2 or more gestational sacs in relation to the total number of pregnancies.
- Deferred transfer:** embryo transfer that does not occur in the ovarian stimulation cycle but in a later one with cryopreserved embryos.
- Abnormal embryo rate:** percentage of abnormal embryos in relation to the number of embryos biopsied



- **NBB per cycle:** percentage of NBB over the total number of procedures.
- **NBB per embryo transferred:** percentage of NBB over the total number of embryos transferred.
- **Single NBB ratio:** percentage of births with a single NBB over the total number of births.



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