

# FRANCE TAVI - Registry for Transcatheter Aortic Bioprosthetic Valve Implantation

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## General

### Identification

Detailed name	Registry for Transcatheter Aortic Bioprosthetic Valve Implantation
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Sign or acronym	FRANCE TAVI
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL no. 912449 on 20/12/2012.
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### General Aspects

Medical area	Cardiology
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Health determinants	Iatrogenic
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Keywords	catheter., Valves
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### Scientific investigator(s) (Contact)

Name of the director	Le Breton
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Unit	Cardiologie Interventionnelle
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Organization	Hôpital
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### Collaborations

### Funding

Funding status	Private
Details	French Cardiology Society.
Governance of the database	
Sponsor(s) or organisation(s) responsible	Société Française de Cardiologie
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Morbidity registers
Database objective	
Main objective	<p>Main objective:: To identify all patients undergoing a valve change by transcatheter implantation, who fulfil the selection and technical criteria, that accept the scheduled assessments as part of the disease and who agreed to participate in the study and survival rate assessment at one year.</p> <p>Secondary objectives: To collect epidemiological data on this new technique.</p>
Inclusion criteria	<ul style="list-style-type: none"> <li>- Aged 18 years or over;</li> <li>- Undergoing a valve change by transcatheter implantation;</li> <li>- Individuals that gave clear consent.</li> </ul>
Population type	
Age	<p>Adulthood (19 to 24 years)</p> <p>Adulthood (25 to 44 years)</p> <p>Adulthood (45 to 64 years)</p> <p>Elderly (65 to 79 years)</p> <p>Great age (80 years and more)</p>
Population covered	Sick population
Gender	<p>Male</p> <p>Woman</p>
Geography area	National

Detail of the geography area	Massy, Caen, Rouen, Brest, Lille, Marseilles, Toulouse, Strasbourg, Saint-Laurent-du-var, Rennes, Le Chesnay, Nantes, Saint-Denis, Paris, Caluire-et-cuire, Angers, Clermont-Ferrand, Tours, Montpellier, Villeurbanne, Bron, Bois-Bernard, Amiens, Montpellier, Bordeaux, Dijon, Grenoble, Poitiers, Pessac, Metz, Le Plessis-Robinson, Mulhouse, Vandoeuvre-Lesnancy and Saint-Etienne.
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	02/2013
Size of the database	
Size of the database (number of individuals)	[1000-10 000[ individuals
Details of the number of individuals	4,016 patients enrolled in 47 centres on 03/06/2014.
Data	
Database activity	Current data collection
Type of data collected	Clinical data Paraclinical data
Clinical data (detail)	Medical registration
Details of collected clinical data	Functional status, medical history, background, pre-implantation assessment, implantation procedure, hospital discharge, complications, vital status, treatment.
Paraclinical data (detail)	Ultrasound.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Participant monitoring	Yes
Details on monitoring of participants	Follow-up at one month then every year.

Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	<a href="http://tinyurl.com/PUBMED-FRANCETAVI">http://tinyurl.com/PUBMED-FRANCETAVI</a>
Description	Liste des publications dans Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only