

# Stent-Save a Life! Argentina Initiative

## *Iniciativa Stent-Save a Life! Argentina*

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### ABSTRACT

**Background:** The Stent-Save a Life! (SSL) initiative is a European program that seeks to improve the access of patients with ST-segment elevation acute myocardial infarction (STEMI) to reperfusion therapies based on clinical guideline recommendations, thus reducing morbidity and mortality.

**Objective:** The aim of this study was to describe the results of the first three years of the SSL Argentina initiative

**Methods:** Initially, a mapping was carried out to analyze the local situation and then the Door-to- Balloon Program (DBP) was developed as a continuous improvement process for centers with primary percutaneous coronary intervention (pPCI) capability.

**Results:** From March 2016 to March 2018, 3,041 patients with STEMI were treated in 38 centers participating in this program. In 20% of cases (n=610) patients had their first medical contact with the emergency medical services. After excluding 184 patients (6%) without coronary lesions, reperfusion therapy was performed in 93% of cases, mainly by pPCI (95%). Total ischemic time was 117 minutes, with differences according to the time of first medical contact. Overall in-hospital mortality was 7%.

**Conclusions:** The lack of a “reperfusion culture” was the common barrier of public and private centers that motivated the development of the DBP. The identification of critical points that prevent treatment on time, together with enhancement of in-hospital organization, represent the first step to improve the care of these patients. The integrated work of all the involved parties is necessary to develop care networks adapted to the local reality of each center and region.

**Key words:** Myocardial infarction - Reperfusion - Angioplasty - Stents- Mortality

### RESUMEN

**Introducción:** La iniciativa *Stent-Save a Life!* (SSL) es un programa europeo que busca mejorar el acceso de pacientes con infarto agudo de miocardio con elevación del ST (IAMCEST) a un tratamiento de reperfusión basado en las recomendaciones de las guías clínicas, reduciendo así su morbilidad y mortalidad.

**Objetivo:** Describir los resultados de los primeros tres años de la iniciativa SSL Argentina

**Material y métodos:** Se realizó inicialmente un mapeo para analizar la situación local y luego se desarrolló el Programa Puerta-Balón (PPB) como un proceso de mejora continua para centros con capacidad de realizar angioplastia primaria (ATCp).

**Resultados:** Desde marzo de 2016 hasta marzo de 2018 se trataron 3041 pacientes con IAMCEST en 38 centros participantes del citado programa. El 20% (n=610) de esos pacientes tuvo su primer contacto médico (PCM) con el servicio de emergencias médicas. Excluyendo los 184 pacientes sin lesiones coronarias (6% del total), el 93% fue reperfundido, principalmente con ATCp (95%). El tiempo global de isquemia fue de 117 minutos, variando según el momento del PCM. La mortalidad global intrahospitalaria fue del 7%.

**Conclusiones:** La falta de una “cultura de reperfusión” fue la barrera en común de centros públicos y privados que motivó el desarrollo del PPB. La identificación de los puntos críticos que impiden un tratamiento a tiempo, junto con la organización de los centros puertas adentro, representan el primer paso para mejorar la atención de estos pacientes. Es necesario el trabajo integrado de todos los actores involucrados a partir de la organización de redes de atención, adaptadas a la realidad local de cada centro y región.

**Palabras clave:** Infarto del miocardio – Reperfusión - Angioplastia - Stents - Mortalidad

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## Abbreviations

<b>PCI</b>	Percutaneous coronary intervention	<b>FMC</b>	First medical contact
<b>pPCI</b>	Primary percutaneous coronary intervention	<b>EMS</b>	Emergency medical services
<b>ECG</b>	Electrocardiogram	<b>SSL</b>	Stent-Save a Life!
<b>STEMI</b>	ST-segment elevation acute myocardial infarction	<b>DBT</b>	Door-to-balloon time
<b>DBP</b>	Door-to-balloon program	<b>ER</b>	Emergency room

## INTRODUCTION

Reperfusion treatment of patients with ST-segment elevation acute myocardial infarction (STEMI) is time-dependent: mortality is lower the faster the culprit artery is reperfused. (1, 2) However, a significant number of patients do not obtain this benefit due to lack of access to a properly organized healthcare system. (3)

Primary percutaneous coronary intervention (pPCI) is the reperfusion treatment of choice, provided it is performed within the time limits recommended by clinical guidelines and experienced operators. (1, 4) For patients who do not have access to such therapy, the clinical guidelines recommend the administration of thrombolytics, followed by a systematic referral for immediate rescue percutaneous coronary intervention (PCI), or a coronary angiography and eventual PCI in the event of positive reperfusion, within 2 to 24 h, as part of a pharmacoinvasive strategy. (1, 5) It has been demonstrated that to achieve a successful outcome, treatment should be regionalized through the creation of networks, connecting hospitals with different levels of complexity with an efficient emergency medical service (EMS), since this increases the proportion of reperfused patients, reduces delays in treatment and, consequently, morbidity and mortality. (6, 7)

The Stent-Save a Life! initiative (SSL) is a European program with unique characteristics, in which all the actors involved in the treatment of STEMI patients work to fulfill the mission of “improving access to a reperfusion treatment that complies with the recommendations of clinical guidelines, thus reducing their morbidity and mortality”. It represents the continuation of the Stent for Life initiative created in 2008 as a coalition between the European Society of Cardiology, the European Association for Percutaneous Cardiovascular Interventions and the EuroPCR, which was developed in 23 countries, mostly in Europe. After the success of this program, it was decided to expand its mission globally with the new name of SSL, adapting to the realities and specific demands of the different regions of the world.

In Argentina, cardiovascular diseases represent the main cause of morbidity and mortality and are responsible for 30% of total deaths; therefore, scientific societies are working to reduce cardiovascular mortality by 25% by the year 2025. STEMI is one of the scenarios that should be confronted to achieve this end, since it represents one of the main causes of mortality

and loss of healthy life years due to premature death or disability. (8)

The aim of this study was thus to present the results of the first three years of the SSL Argentina initiative, divided into two stages: the first, was the mapping stage and identification of local barriers, and the second was the introduction of the door-to-balloon program, in order to overcome some of these barriers.

## METHODS

During 2015, an analysis of the local situation was carried out with the purpose of identifying the barriers that prevent patients from receiving a quality and timely reperfusion treatment. Web surveys were sent to centers with or without capability to perform PCI, and this allowed for the analysis of available resources. A total of 292 centers throughout the country answered the survey (228 capable of performing pPCI).

After identifying the most important barriers, the door-to-balloon program (DBP) was created, devised as a process of continuous improvement so that the participating centers can provide a quality reperfusion treatment in accordance with clinical guideline recommendations, regardless of whether they are private or public.

Currently, 46 centers of 11 provinces (Buenos Aires, Santa Fe, Catamarca, Santiago del Estero, Corrientes, Córdoba, Chaco, Mendoza, Tucumán, Entre Ríos and Santa Cruz) capable of performing pPCI take part in this program. The participating centers and the requirements that the centers had to meet in order to participate in the program are detailed in the appendix.

In each center, the creation of work teams with all the actors involved in the care of STEMI patients was stimulated. All patients with suspected STEMI established within 48 h of symptom onset were included in a common database with the purpose of evaluating time until treatment. A monthly global blind report was sent to each center with the comparison of his door-to-balloon time (DBT) and that of the rest of the centers, in addition to an individual report in which times until treatment were indicated according to the first medical contact (FMC) and suggestions were offered to improve them. This information allows the centers to analyze their performance and represents the basis to stimulate the development of local strategies adapted to the reality of each center, and the generation of a “reperfusion culture” in its participants.

We present the most relevant results of the first two years of the DBP performance, involving the patients treated in 38 participating centers.

## Statistical analysis

Continuous variables are expressed as mean and standard deviation or median and interquartile range (IQR), according to their distribution, and categorical variables are expressed as numbers and percentages.

Student's test or the Wilcoxon rank sum test were used to compare between groups, as appropriate. Proportions were compared using the chi square test or Fisher's exact test, according to the frequency of expected values. In all cases, an alpha error of 5% was assumed to establish statistical significance. Epi Info 7.2 software was used for the statistical analysis.

### Ethical considerations

All patients signed the informed consent form of each participating institution.

## RESULTS

### Mapping phase

The main barriers identified were the following:

1. The Argentine Republic has a highly fragmented healthcare system with little integration of the sectors involved.
2. As a result, there are multiple centers and MES of different complexity and quality of care, lacking organization and adequate resources to facilitate a prompt diagnosis and treatment of these patients.
3. There is scarce reperfusion culture in the medical and even cardiological community, understood as a lack of commitment to reperfuse patients within the times recommended by the clinical guidelines, so that treatment of infarction is dependent on personal or certain care center initiatives.
4. There are sufficient centers with hemodynamics laboratories to satisfy the demand at a national level, but these are concentrated in cities with a high population density, leaving a large part of the territory uncovered.
5. There are no basic guidelines at a national level to treat these patients, or a universal telephone number for medical assistance.
6. Streptokinase, a non-fibrin-specific thrombolytic agent is used in more than 95% of cases, with a lower success rate.
7. There are few formal networks: the public hospital networks of the city of Buenos Aires and the city of Rosario are a few examples. These networks arose from personal concerns to improve the treatment of these patients and have progressed thanks to the efforts of their coordinators.
8. There is no education in the population regarding the symptoms suggestive of infarction and the actions to be taken for a prompt access to the healthcare system.

### Door-to-balloon-program

A total of 3,041 patients with suspected STEMI, admitted to 38 centers with 24/7 pPCI throughout the country, were included in the study from March 2016 to March 2018. Baseline population characteristics after excluding patients with normal coronary arteries (n=2,857) are described in Table 1.

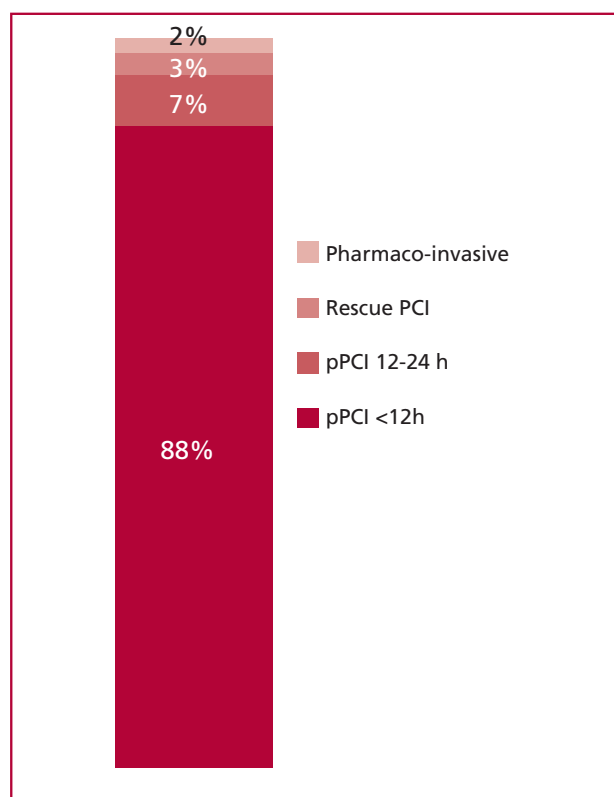
### First medical contact

In 20% of cases (n=610), patients called the MES from their home and in almost half of them (n=294) a pre-hospital electrocardiogram (ECG) was performed. Thirty percent of all these cases (n=183) pre-activated the hemodynamics lab, and 17.3% (n=106) were transferred to centers without hemodynamics, albeit having a center with pPCI capability in the same city. The remaining patients arrived by their own means

**Table 1.** Population characteristics

Total n	2,857	
Age (mean±SD)	61±11	
Male gender	2,303	(81%)
CRF		
HTN	1,944	(68%)
DLP	1,316	(46%)
Smoking	1,217	(42%)
DBT	621	(22%)
Previous PCI	372	(13%)
Previous CABG	56	(2%)

CRF: Cardiovascular risk factors. HTN: Hypertension. DLP: Dyslipidemia. DBT: Diabetes. PCI: Percutaneous coronary intervention. CABG: Coronary artery bypass grafting



**Fig. 1.** Reperfusion strategy in patients treated with primary percutaneous coronary intervention (n=2,641). PCI: Percutaneous coronary intervention. pPCI: Primary percutaneous coronary intervention.

to centers with or without pPCI capability [ $n=1,238$  (41%) and  $n=1,192$  (39%), respectively].

#### Reperfusion treatment and time to treatment

After excluding 184 patients (6%) without significant coronary lesions, PCI was the reperfusion treatment performed in 92% of patients (Figure 1).

Median DBT of patients treated with pPCI and rescue PCI ( $n=2,354$ ) was 60 minutes (IQR: 39-91). This time, which varied according to the FMC, was shorter in patients who arrived to the center with pPCI by ambulance from their home [53 min (IQR: 35-76)] or were referred from another center [42 min (IQR: 26-65)] compared with patients who consulted spontaneously in centers with pPCI [81 min (IQR: 58-117),  $p < 0.01$ ].

The time to treatment (from FMC to balloon) in the global population was 117 min (IQR: 77-185), but when analyzed according to the type of FMC, 24.5% ( $n=104$ ) of patients who arrived by ambulance from

their homes were reperfused within 90 minutes of FMC; 22% ( $n=192$ ) of those who were referred from centers without PCI were reperfused within 120 minutes of FMC; and 27% ( $n=293$ ) of those who entered directly to a center with pPCI were reperfused within 60 min. (Figure 2).

#### In-hospital mortality

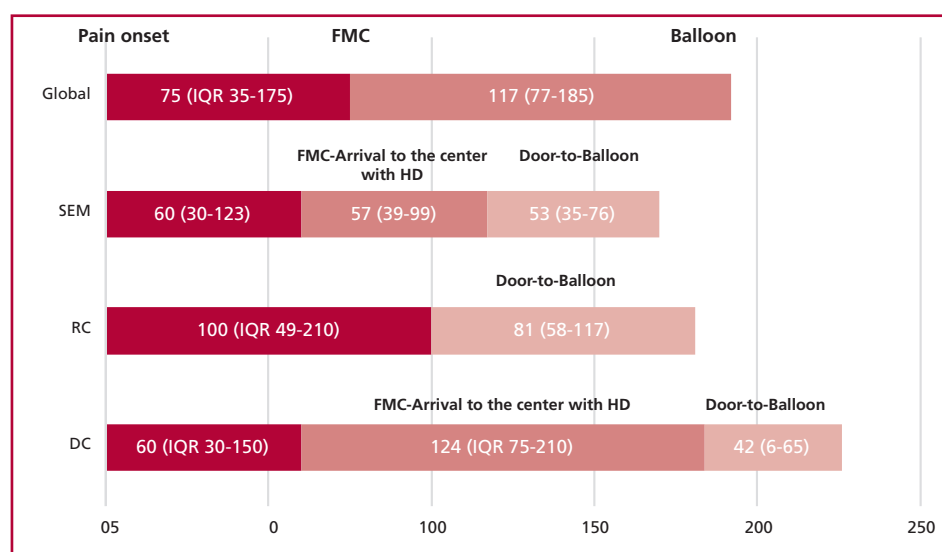
Overall in-hospital mortality was 7% ( $n=200$ ). Figure 3 shows the in-hospital mortality according to the reperfusion treatment established.

Mortality according to the Killip and Kimbal classification was 1.6%, 7%, 24% and 51% for class A, B, C and D, respectively.

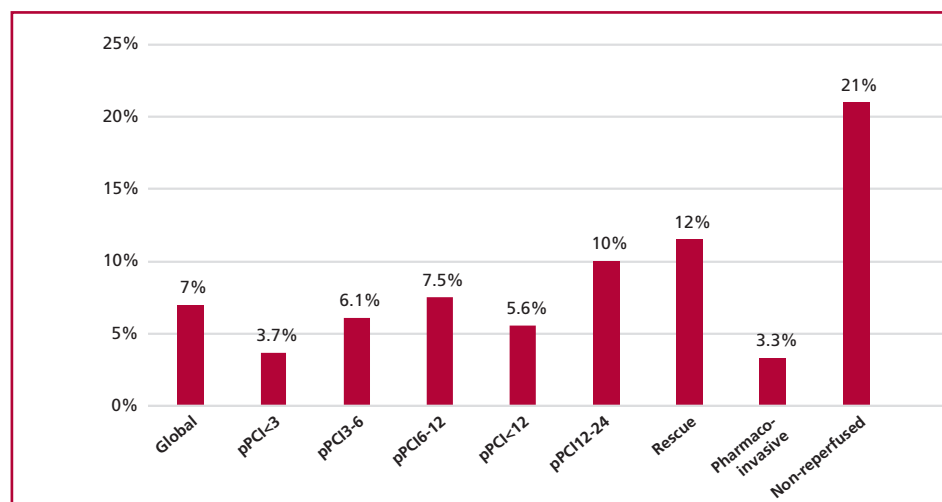
#### DISCUSSION

Knowing the reality of care of patients with STEMI is the first step to establish why they often do not receive a quality and timely reperfusion treatment.

In a country with a fragmented healthcare system



**Fig. 2.** Reperfusion times according to first medical contact. HD: Hemodynamics. MES: Medical emergency services. RC: Receiving center. DC: Derivation center.



**Fig. 3.** Global in-hospital mortality and according to the reperfusion treatment adopted. pPCI: Primary percutaneous coronary intervention.

and with multiple barriers, as the ones mentioned above, it is difficult to implement generalized measures tending to develop an “Infarction Code” adaptable to the reality of each region without a joint work with the healthcare authorities.

This situation could explain the 9% global mortality observed in the Argen-IAM ST registry, without a clear reduction compared with previous records. (9, 10)

Each center, city, region or province may have one or more of these barriers, and knowing them represents the first step to understand the local reality and generate strategic actions to improve the treatment of patients with STEMI.

Mapping allowed us to recognize the most important barriers and to find points that link public and private centers despite their differences in order to start working: one of them was the lack of reperfusion culture and, consequently, the limited indoor organization.

Patients participating in the DBP of the SSL Argentina initiative comprise the largest series of patients with STEMI analyzed in our country, and represents an attempt to show the reality of 38 centers with the capacity to perform pPCI 24/7. Unlike a standard registry, the SSL initiative systematically collects and analyzes the time until treatment of patients with STEMI within the framework of a continuous improvement program, never before done in our country. The possibility of comparing each center with others creates a culture of reperfusion and action awareness, stimulating the generation of activities to improve their own results.

The current paradigm of STEMI patients' management is based on treatment regionalization with the creation of networks and on the transfer of the diagnosis of infarction to the prehospital stage, with the aim of reducing time to treatment.

The clinical guidelines recommend MES to be the access door to the healthcare system and discourage patients from going to the centers by their own means due to the risk of presenting malignant arrhythmias during the transfer, and because those who enter by ambulance from their homes get a faster assistance and avoid waiting in the emergency room (ER). (1)

This analysis shows that only 20% of patients with suspected STEMI called MES to request medical assistance, a figure well below the reality of other European countries participating in the SSL initiative. (11) The lack of ECG in some ambulances and the absence of transfer methodologies explain that only 48% of the patients who called MES underwent a diagnostic ECG, and that 17.3% of the patients were transferred to a center without PCI, despite having a center with hemodynamics lab in the same city.

The preactivation of the center with hemodynamics lab is a strategy that reduces DBT, by allowing not only the hemodynamics team to arrive before the patient, but also that once the patient arrives at the

center he is directly transferred to the catheterization room avoiding his passage through the ER. (12,13)

These two strategies would explain the lower DBT observed in patients admitted to centers with PCI by ambulance from another center or from their home, compared with those who consulted spontaneously in the ER.

The DBT of patients who consult the ER of centers with hemodynamics lab could be improved with actions that guarantee a quick ECG, prioritizing the care of patients with symptoms suggestive of infarction and thus facilitating a prompt activation of the hemodynamics team.

Although median DBT of patients arriving by ambulance was less than 60 minutes, for these patients, DBT is only a component of the time until treatment.

The time of the analyzed system was suboptimal, since 24.5% of the patients who arrived by ambulance from their home were reperfused within 90 minutes of FMC and 22% of those who were hospitalized from centers without pPCI did so within 120 minutes of FMC, as recommended by clinical guidelines. (1)

This shows the absence of networks and the deficiencies of our system to coordinate the transfer of patients with STEMI.

Overall in-hospital mortality was 7% and represents the lowest global mortality reported in our country.

This could be explained by the fact that these are centers with PCI, where pPCI was the reperfusion treatment used in 92.4% of patients, and in 88% of cases it was performed within 12 h of symptom onset.

Reperfusion treatment is time-dependent, which is demonstrated by an in-hospital mortality of 3.7% when pPCI is performed within 3 h of symptom onset, 6.1% when it is performed between 3 and 6 hours, and 7.5% when done between 6 and 12 h. The RADAC registry reported in-hospital mortality of 4.3% for the subgroup of patients with STEMI, but without stating the time-to-treatment, thus making comparisons difficult. (14)

Beyond the lower overall mortality observed, it is important to highlight the low mortality of patients treated with a pharmaco-invasive strategy (3.3%). In a large country such as Argentina, with centers with pPCI distributed mainly in large cities, the pharmaco-invasive strategy could play an important role in attempting an increase in the number of reperfused patients and allowing more flexible referral times. However, this strategy is not systematically applied and in our population it was used in 2% of cases, similarly to data from the Argen-IAM ST registry. (9)

The use of streptokinase could be a barrier for developing this strategy; however, countries such as India have managed to develop networks based on the Hub and Spoke model, where each region has a receiving hospital with the capacity to perform pPCI 24/7 (hub) and derivation centers (spokes), which, depending on the distance to the hub, refer patients to



pPCI or perform a pharmaco-invasive strategy using streptokinase. (15) Models such as this one have been shown to reduce mortality at 1 year by 25% and will be taken as an example to develop networks in low and middle income countries. (16)

### Limitations

We cannot fail to mention as a limitation that this is the experience of 38 centers with the capacity to perform pPCI 24/7, so these results cannot be generalized.

### CONCLUSIONS

The SSL initiative seeks to improve the access of patients with STEMI to a reperfusion treatment that complies with the recommendations of clinical guidelines.

The identification of the barriers that prevent patients from receiving a timely treatment and the shortcomings in the centers' indoor organization represent the first step to improve the care of these patients, which requires the integrated work of all the actors involved.

The active and continuous participation in this type of initiatives will allow developing strategies to create networks adapted to the local reality of each center and region.

### Conflicts of interest

None declared. (See authors' conflicts of interest forms on the website/Supplementary material).

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## APPENDIX

### Centers participating in the Stent-Save a Life! Argentina initiative and its coordinators, ordered by provinces:

- **Buenos Aires:** Hospital Italiano de La Plata (Dr. Andrés Pascua, Dr. Agustín Hauqui), Hospital Español de La Plata (Dr. Diego Grinfeld, Dr. Sebastián Amicone), Instituto Médico Platense (Dr. Nicolás Nitti, Dr. Diego Ríos), Sanatorio Argentino (Dr. Guillermo Cugat, Dr. Agustín Dettbarn), Hospital San Juan de Dios (Dr. Guillermo Mulinaris), Instituto de Diagnóstico (Dra. Elisabeth Marsiglio), Hospital San Martín (Dr. Nicolás Nitti, Dr. Dario Cavalie), Sanatorio Las Lomas (Dr. Pablo Stutzbach, Dr. Luciano Destefano), Sanatorio Anchorena San Martín (Dr. Gustavo Pedernera, Dr. Leandro Rodríguez).
- **Catamarca:** Sanatorio Pasteur (Dra. Lorena Villagra), Sanatorio Junín (Dra. Lorena Villagra).
- **Chaco:** Instituto Cordis (Dr. Eduardo Ferro Queirel).
- **Ciudad Autónoma de Buenos Aires:** Instituto Cardiovascular de Buenos Aires (Dr. Fernando Cura), Sanatorio Anchorena (Dr. Pablo Spaletta, Dr. Nicolás Lalor), Hospital Italiano de Buenos Aires (Dr. Daniel Berrocal, Dr. Fernando Cohen), Fundación Favalaro (Dr. Ernesto Duronto, Dr. Carlos Fava), Hospital Británico (Dr. Guillermo Migliaro), Hospital Alemán (Dr. Guillermo Migliaro), Hospital General de Agudos Dr. Juan A. Fernández (Dr. Pablo Perez Baliño, Dra. Verónica González), Hospital General de Agudos Dr. Cosme Argerich (Dr. Alejandro Escudero, Dra. Analía Alonso), Hospital General de Agudos Bernardino Rivadavia (Dr. Alfredo Hirschson Prado, Dr. Rodrigo Alderete), Sanatorio Guemes (Dr. Marcelo Bettinotti, Dr. Rodrigo Villarreal), Sanatorio de la Trinidad Palermo (Dr. Alejandro Palacios, Dra. María Daniela Coria), Clínica San Camilo (Dr. Aldo Rodríguez Saavedra, Dr. Sebastián Peralta), Hospital General de Agudos Francisco Santojanni (Dr. Rubén Kevorkian, Dra. Natacha Ruiz).
- **Córdoba:** Sanatorio Allende Cerro (Dr. Lucas Maldonado, Dr. Guillermo Pacheco).
- **Corrientes:** Instituto de Cardiología de Corrientes “Juana F. Cabral” (Dr. César Rodrigo Zoni).
- **Entre Ríos:** Sanatorio Garat (Dr. Federico Graziano), Hospital San Martín (Dr. Martín Hermida), Sanatorio San Lucas (Dr. Emiliano Luchessi).
- **Mendoza:** Hospital Central de Mendoza (Dr. Leonardo Ripa, Dr. Pablo García).
- **Santa Fe:** Hospital Provincial del Centenario (Dr. Pedro Zangroniz, Dr. Lucas Arias), Instituto Cardiovascular de Rosario (Dr. Aníbal Damonte, Dr. Leandro Lasave), Sanatorio Esperanza (Dr. Jorge Allín), Sanatorio Británico (Dr. Tomás Cuneo, Dr. Daniel Zanuttini), Sanatorio Nosti (Dr. Adrian Ingaramo, Dr. Eduardo Herrera), Sanatorio Plaza (Dr. Tomás Cuneo, Dr. Marcelo Menéndez), Hospital Provincial Dr. Jose M. Cullen (Dr. Rubén Retamar, Dr. Agustín Roude), Sanatorio Privado San Gerónimo (Dr. Oscar Birollo), Hospital Privado de Rosario (Dra. Maria Belén Cigalini, Dr. Claudio Cigalini), Hospital Español (Dr. Daniel Paolantonio), Clínica de Nefrología, Urología y Enfermedades Cardiovasculares (Dr. Oscar Birollo).
- **Santa Cruz:** Hospital Regional Río Gallegos (Dra. Corina Biagioni, Dr. Alejandro Cherro).
- **Santiago del Estero:** Instituto de Cardiología (Dr. Santiago Coroleu), Clínica Yunes (Dr. Jorge Trejo, Dr. Emanuel Sarnago).
- **Tucumán:** Instituto de Cardiología (Dr. Arturo Fernández Murga, Dr. Jose Cruzado).

### Center requirements to join the program:

1. Availability to perform pPCI 24/7.
2. Commitment to work in order to meet the objectives of the Stent Save a Life! Argentina initiative.
3. Creation of a multidisciplinary work team that includes, as minimum, Emergency, Clinical Cardiology (UOC/UTI) and Hemodynamics medical personnel.
4. Establish a systematic care of patients with STEMI following the recommendation of clinical guidelines.
5. Record the times to reperfusion treatment in a mandatory manner on a common database.
6. Allow monitoring of the data entered.