



Functional versus Culprit-only Revascularization in Elderly Patients with Myocardial Infarction and Multivessel Disease: the **FIRE Trial**



1st birthday

Journal Pre-proof

Physiology-guided revascularization versus optimal medical therapy of non-culprit lesions in elderly patients with myocardial infarction: Rationale and design of the FIRE trial

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PII: S0002-8703(20)30237-4

DOI: <https://doi.org/10.1016/j.ahj.2020.08.007>

Reference: YMHI 6209

To appear in: *American Heart Journal*



Our Roadmap – before COVID19

Start enrolment August 2019

Methodological Manuscript November 2019

Italy-Poland-Spain FIRE meeting EuroPCR (May) 2020

700° enrolled patient May 2020 (EuroPCR ???)

End enrolment December 2020

End primary endpoint follow-up December 2021

Main result presentation/publication ESC (August) 2022

Subanalyses, substudies, extended follow-up 2022-2026



Our Roadmap – after/during COVID19

Start enrolment August 2019

Methodological Manuscript August 2020

700° enrolled patient October 2020

End enrolment August 2021

End primary endpoint follow-up August 2022

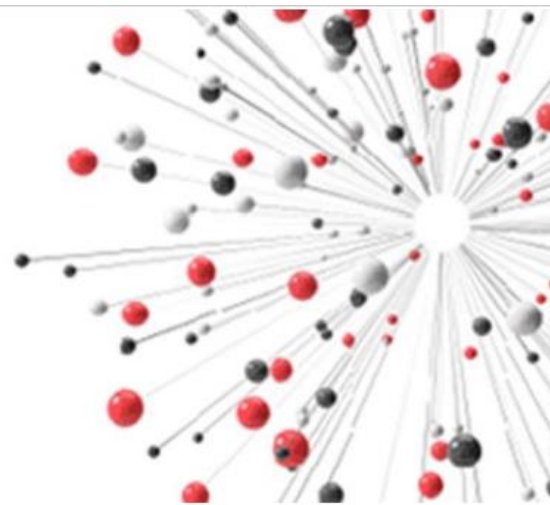
Main result presentation/publication ESC (August) 2023

Subanalyses, substudies, extended follow-up 2023-2027



Why FIRE trial is needed

ESC Congress
The Digital Experience
Bringing the world of cardiology together
29 August to 1 September
#ESCcongress



What do they say regarding the topic of the fire trial?

13 Gaps in evidence for non-ST-segment elevation acute coronary syndrome care and future research

Gaps in NSTEMI-ACS Care	Needed RCTs
TIMING OF ANGIOGRAPHY AND REVASCULARIZATION STRATEGIES	
Mainly due to difficulties in enrolment, older patients have been under-represented in clinical trials of invasive strategies for NSTEMI-ACS patients.	Multicentre RCTs evaluating the safety and effectiveness of different treatment strategies in sufficient numbers of older NSTEMI-ACS patients.
It remains unclear whether coronary revascularization of the presumed culprit lesion only or complete revascularization in NSTEMI-ACS patients should be attempted.	RCTs of PCI of the presumed culprit lesion only based on non-invasive imaging and/or coronary angiography vs. complete revascularization with PCI (or CABG).
The value of haemodynamic assessment based on FFR of non-culprit lesions to guide complete revascularization in the NSTEMI-ACS setting remains unclear.	Patients presenting with NSTEMI-ACS and multivessel disease randomized to PCI as indicated with vs. without FFR of non-culprit lesions.





Current status



AN OVERVIEW ON ITALY (n=18)



CENTERS	ACTIVE FROM	TARGET	N° OF PATIENTS ENROLLED	% ACHIEVED
FERRARA	18/07/2019	60	181	100%
REGGIO EMILIA	30/08/2019	53	118	100%
TORINO RIVOLI	12/11/2019	43	35	81%
MESTRE	10/08/2020	5	4	80%
BOLOGNA MAGGIORE	14/10/2019	47	35	75%
RIMINI	28/10/2019	45	27	60%
LA SPEZIA	25/08/2020	4	2	50%
RAVENNA	04/11/2019	44	18	41%
SIRACUSA	12/12/2019	39	14	36%



CENTERS	ACTIVE FROM	TARGET	N° OF PATIENTS ENROLLED	% ACHIEVED
MODENA BAGGIOVARA	19/11/2019	42	14	33%
MCH COTIGNOLA	10/01/2020	35	11	31%
GROSSETO	15/05/2020	17	5	29%
PALERMO GIACCONE	20/02/2020	29	7	24%
MADDALONI	28/11/2019	41	5	13%
AGRIGENTO	18/01/2020	34	5	14%
CATANIA	25/05/2020	15	1	7%
NAPOLI CARDARELLI				
VERONA BORGO TRENTO				
MESSINA POLICLINICO				



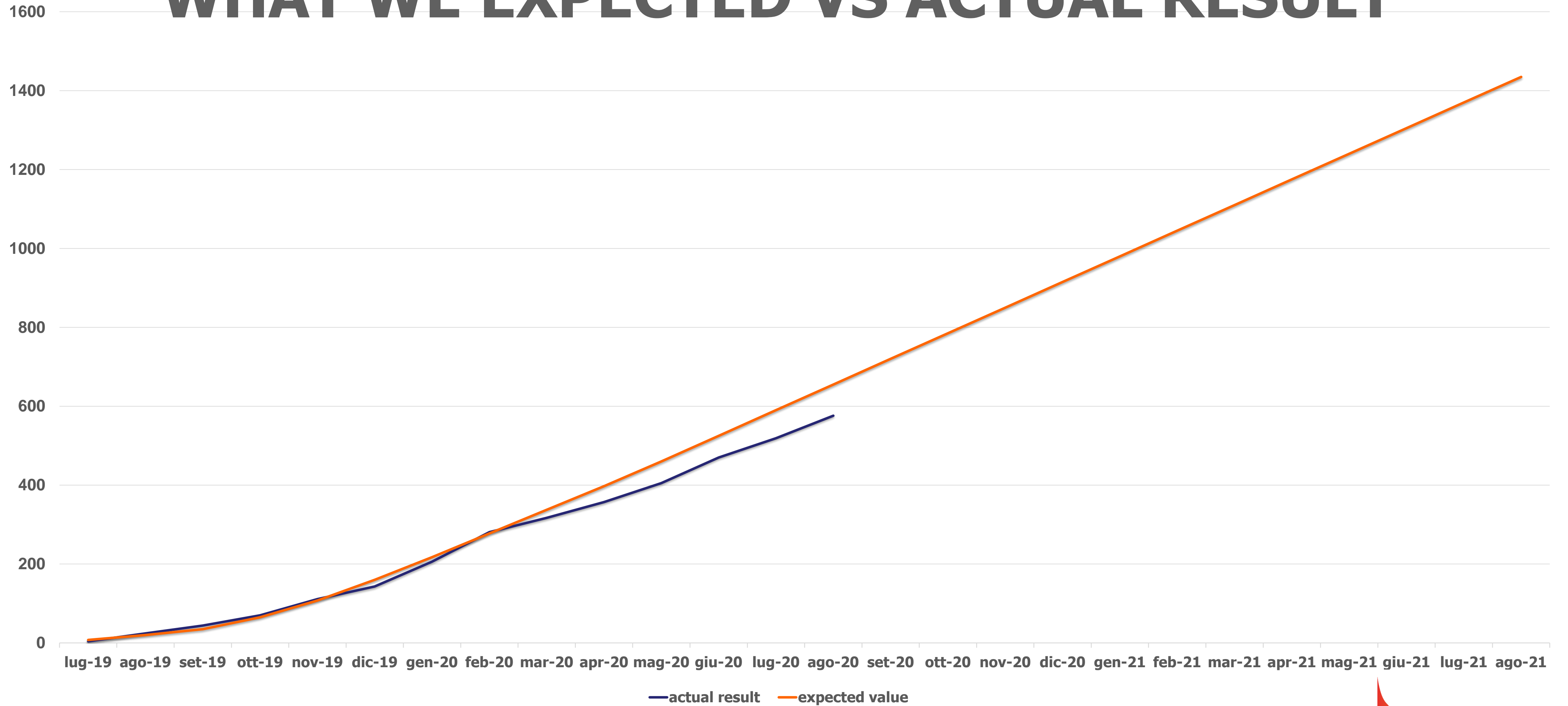
AN OVERVIEW ON SPAIN (n=10)



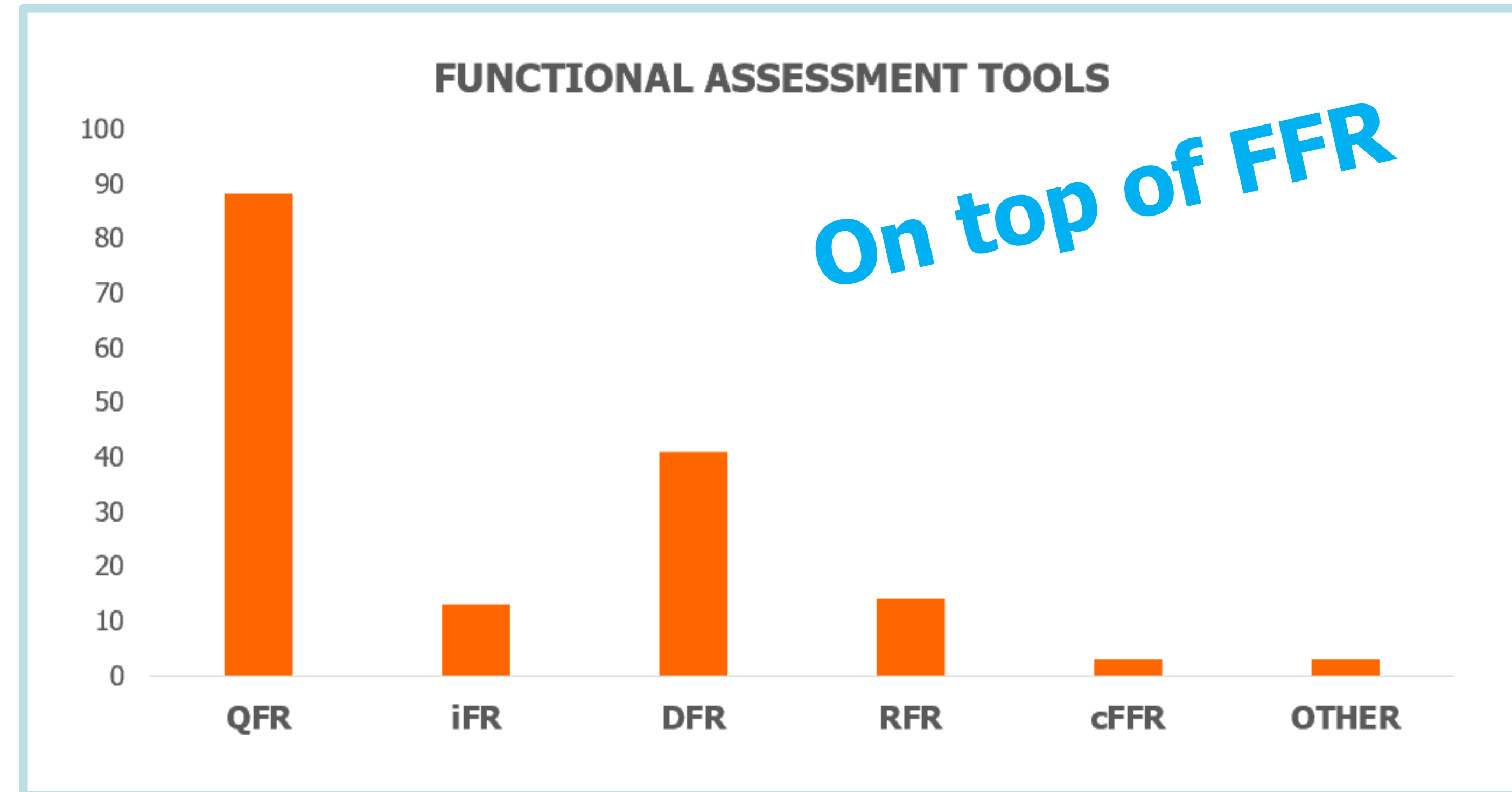
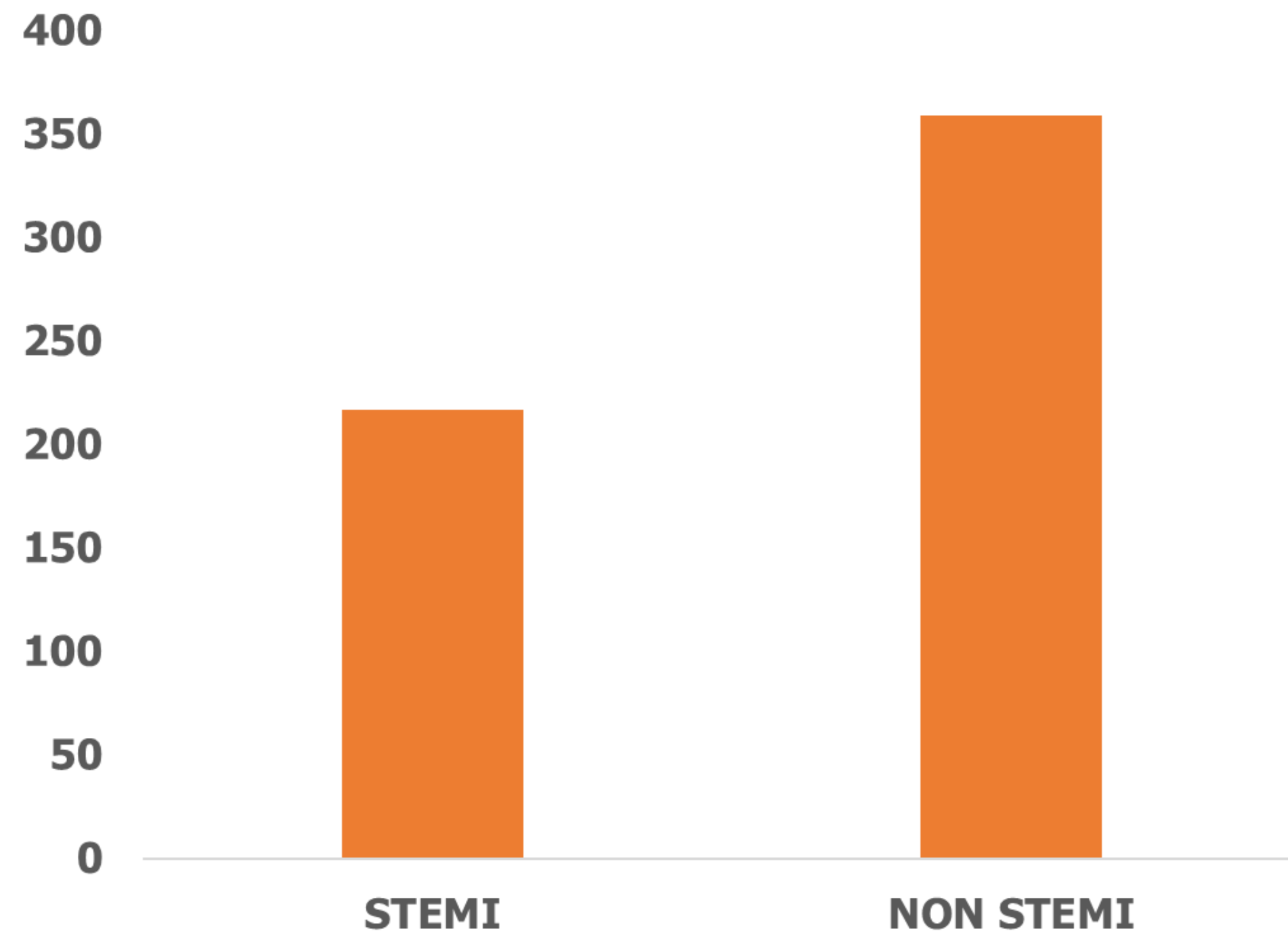
CENTERS	WEEKS IN ACTIVITY	TARGET	N° OF PATIENTS ENROLLED	% ACHIEVED
MADRID LA PAZ	22/10/2019	47	19	40%
VALENCIA	21/12/2019	38	14	37%
MADRID MARANON	13/08/2019	57	18	32%
VALLADOLID	25/07/2019	60	18	30%
SANTIAGO	03/10/2019	50	11	22%
MADRID HCS	31/07/2019	59	12	20%
VIGO	25/10/2019	47	6	13%
CIUDAD REAL	19/09/2019	52	4	8%
LA CORUNA	04/11/2019	49	4	8%
LUGO	01/10/2019	50	3	6%



WHAT WE EXPECTED VS ACTUAL RESULT



A FEW NUMBERS BY AUGUST 2020



ENROLLED PATIENTS	STEMI	NON STEMI
576	217	359

Monitoring of Adverse Events

PRIMARY ENDPOINT (JULY 2020) – MEDIAN FUP VALUE

CUMULATIVE MONTHS OF FUP	N° OF PATIENTS ENROLLED	MEDIAN FUP VALUE
2947	519	5,7

SERIOUS ADVERSE EVENTS

DEATH	ANY MI	STROKE	ANY REVASCULARIZATION
17	7	3	4