

## From the PI's Desk



Pamela Douglas, MD, MACC,  
FASE, FAHA  
Duke University Clinical  
Research Institute  
Durham, NC USA  
Principal Investigator  
PLATFORM

Dear PLATFORM  
Investigators,

Welcome to the first edition of the PLATFORM Newsletter. I am pleased to report that we are off to an extremely good start with the first subject enrolled on September 10, 2013, at Centro Cardiologico Monzino, Milan, Italy. We now have 3 active clinical sites with a total of 140 subjects enrolled. We have also enrolled 15 subjects in Cohort 2.

The PLATFORM study is a highly important next step for the development of cardiovascular diagnostic testing in general and FFR<sub>CT</sub> technology in particular. As the paradigm of coronary artery disease assessment and treatment is evolving to better appreciate the importance of coronary physiology as well as anatomy, it is critical that diagnostic testing rise to this challenge. FFR<sub>CT</sub> has already demonstrated tremendous potential to non-invasively assess these important characteristics. The PLATFORM study will provide much needed real world information about how diagnostic pathways and clinical care can be altered by state of the art non-invasive testing.

With this newsletter, the goal is to provide valuable information to you to promote speedy enrollment and clean data entry for an ultimately successful study outcome. Should you have any questions, please feel free to reach out to me, Dr. Pontone or any of the HeartFlow PLATFORM team.

Best regards,  
Pamela S. Douglas MD, MACC, FASE, FAHA  
Principal Investigator  
E: [Pamela.douglas@duke.edu](mailto:Pamela.douglas@duke.edu)  
T: 919 401 4155

## Top Enrolling Site:

### Centro Cardiologico Monzino; Milan, Italy

The top enrolling site in the PLATFORM study is Centro Cardiologico Monzino which has enrolled 67 subjects with Coordinator Site Study PI and PLATFORM Steering Committee member Dr. Gianluca Pontone as the site's PI. When asked what the secret to success is enrolling such a large number of subjects in a short period of time, Dr. Pontone said, "A systematic screening methodology for all patients referred to our hospital with potential characteristics for PLATFORM is the basis for this huge rate of enrollment."

*"More specifically, all lists of patients scheduled for non-invasive testing or already scheduled for invasive coronary angiography are checked. When patients meet the inclusion criteria for the study we contact the reference physician and if he approves, we call the patient to explain the study and to ask if he wishes to be part of this exciting project. The true key to this strategy is the great enthusiasm of my co-investigators and in particular, Dr. Erika Bertella, who is coordinating the screening strategy."*



(Continued on Page 2)

# The PLATFORM Study Newsletter

Prospective Longitudinal Trial of FFR<sub>CT</sub>: Outcome and Resource Impacts

## Top Enrolling Site - Continued

Dr. Pontone went on to state, “The PLATFORM study is a great opportunity to understand the true usefulness of FFR<sub>CT</sub> in the clinical decision making process. The most amazing aspect is that you don’t need to plan a further exam, but the entire process is included in a one shot scan. We are thrilled to be using FFR<sub>CT</sub> and eagerly await the outcome of the study.”



Centro Cardiologico Monzino is an institute fully dedicated to clinical and research activity, focused on cardiovascular disease. Located within the hospital, are the academic course of medicine, the school of cardiology, and cardiac surgery of the University of Milan. Moreover, several other training courses are organized each year with a well-established program on cardiac imaging. At a rate of about 4000 catheterizations and more than 2000 cardiac CT scans performed each year, the Centro Cardiologico Monzino is placed among the leading international centers in the field of cardiovascular disease.

## PLATFORM Enrollment

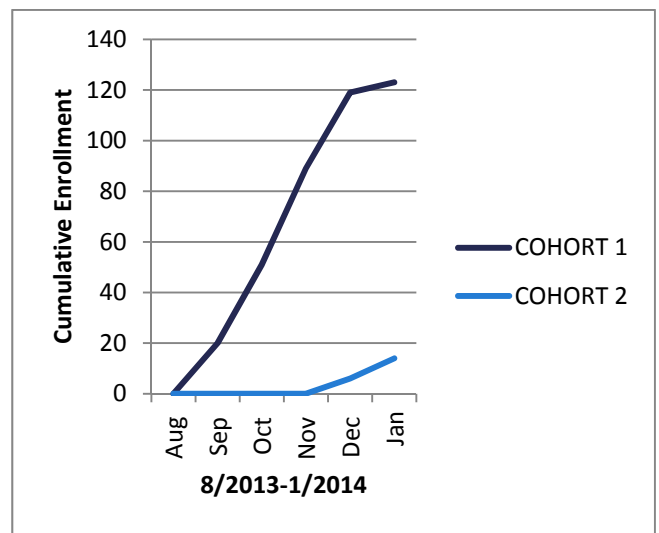
### Overall Enrollment = 140 Subjects

The table below shows the study’s overall enrollment. As you can see, all three sites have done an outstanding job at recruitment and enrollment of subjects. Milan enrolled the first subject in Cohort 2 on 13 December 2013. Aarhus should also be starting enrollment in Cohort 2 in the next few weeks. Several more sites should be ready to begin enrollment very soon.

Site Name	# Subjects Enrolled – Cohort 1	# Subjects Enrolled – Cohort 2	Total # Subjects Enrolled	% of Total Enrolled
19-Aarhus-DK	55	0	55	39%
29-Milan-IT	52	13	67	48%
30-Munich-GER	18	0	18	13%

The graph below shows the current PLATFORM enrollment over time. Our goal is to have the PLATFORM Study fully enrolled by July 31, 2014.

PLATFORM Enrollment



## Updated Diamond Forrester Reference Table

Some of the sites have asked questions about the Updated Diamond Forrester (UDF) Risk Scores and how these are calculated. Subjects must have a UDF Risk Score between 20% and 80% to be eligible for enrollment.

For your reference, we would like to provide the modified table below:

Age	Non-anginal chest pain		Atypical Angina		Typical Angina	
	Men	Women	Men	Women	Men	Women
30 – 39	17.7	5.3	28.9	9.6	59.1	27.5
40 – 49	24.8	8.0	38.4	14.0	68.9	36.7
50 – 59	33.6	11.7	48.9	20.0	77.3	47.1
60 – 69	43.7	16.9	59.4	27.7	83.9	57.7
70 – 79	54.4	23.8	69.2	37.0	88.9	67.7
>80	64.6	32.3	77.5	47.4	92.5	76.3

Table modified from: Genders TS, Steyerberg EW, Alkadhi H, Leschka S, Desbiolles L, et al. Eur Heart J.2011 Jun;32(11):1316-1330. doi:10.1093/eurheartj/ehr014.

This table is also available in your Pocket Reference Cards and we would be happy to provide you with the original reference paper, upon request.

## ESC Guidelines – chest pain classification

The topic of defining classification of angina for determination of the Updated Diamond Forrester Score came up during the Investigator’s Meeting in Brussels, Belgium back in November and was discussed at some length. To assist with this discussion, we have included below the summarized definitions for the traditional clinical classification of chest pain taken from the ESC guidelines article of 2013.<sup>1</sup>

Typical angina (definite)	Meets all three of the following characteristics: • substernal chest discomfort of characteristic quality and duration; • provoked by exertion or emotional stress; • relieved by rest and/or nitrates within minutes.
Atypical angina (probable)	Meets two of these characteristics.
Non-anginal chest pain	Lacks or meets only one or none of the characteristics.

<sup>1</sup> Table from: Montalescot G, et al. “2013 ESC Guidelines on the management of stable coronary artery disease” Eur Heart J. 2013 Aug;doi:10.1093/eurheartj/ehs296

Remember to document the chest pain classification and UDF score on the source documents when enrolling each subject.

## Important Study Updates

Please note this important clarification to the study protocol in regards to which angiograms are to be sent to the QCA Core Lab for analysis of the primary endpoint (Cohort 1 vs. Cohort 2: percentage of negative ICAs performed [assessed at 90 days]):

- Angiograms from the primary ICA procedure with at least one stenosis  $\geq 40\%$  by site visual estimation will be sent to the QCA Core Lab.

If you have any questions on this or any other aspect of the protocol, please do not hesitate to contact us.

## Contact Information

**Ashleigh Willson**  
Clinical Research Manager  
Office: +1 (650) 779-4872  
[awillson@heartflow.com](mailto:awillson@heartflow.com)

**Dustin Michaels**  
VP Clinical, Quality & Regulatory Affairs  
Office: +1 (650) 241-4247  
[dmichaels@heartflow.com](mailto:dmichaels@heartflow.com)

**Auben Debus**  
Senior Clinical Research Associate  
Office: + 1 (650) 779-4875  
[adebus@heartflow.com](mailto:adebus@heartflow.com)

**Katelyn Patterson**  
Clinical Research Associate  
Office: +1 (650) 779-4838  
[kpatterson@heartflow.com](mailto:kpatterson@heartflow.com)

**Ben Forrest**  
Senior Manager, Market Strategy  
Office: +1 (650) 779-4778  
[bforrest@heartflow.com](mailto:bforrest@heartflow.com)

**Susan Engelson**  
Market Access Specialist  
Office: +1 (650) 779-4780  
[sengelson@heartflow.com](mailto:sengelson@heartflow.com)

**Scott Gellert (Monitoring Director)**  
President, Clinical Consulting  
5026 Zimmer Cove, San Diego, CA 92130  
Phone: +1 (858) 792-6830  
[scott@clinreg.com](mailto:scott@clinreg.com)

**Campbell Rogers, MD (SAE Reporting)**  
Chief Medical Officer  
Office: +1 (650) 779-4777  
[crogers@heartflow.com](mailto:crogers@heartflow.com)