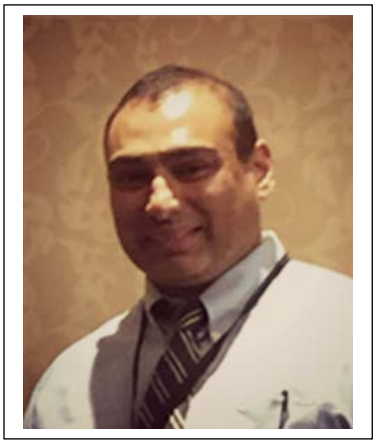
ATACH-II
Antihypertensive Treatment of Cerebral Hemorrhage

Volume 1, Issue 14 | July 2016

Farewell from Dr. Qureshi, Principal Investigator for ATACH-II

Dear ATACH-II Colleagues:



Thanks to all of you for your support and commitment to the ATACH-II Clinical Trial. This trial successfully enrolled a total of 1,000 subjects from 110 domestic and foreign sites. These sites are in six different countries consisting of the United States, Japan, China, Taiwan, Germany and South Korea.

The first subject for ATACH-II trial was enrolled on May 15, 2011, at Abington Memorial Hospital, USA and the 1000th subject was enrolled on September 14, 2015 in Shin-Kong Wu Ho-Su Memorial Hospital, Taiwan. As you may be aware, the primary results of the ATACH-II trial were published "online first" in The New England Journal of Medicine on June 9, 2016. I am happy to report that there have been 107,213 page views for the online publication with 12 media coverage as of 5th August, 2016. The article ranks at 98th percentile compared to other New England Journal of Medicine publications.

It was a pleasure to meet with all of you who attended the Final Investigators' Meeting in Honolulu, Hawaii in April. This was a very productive meeting that resulted in detailed discussions of several key topics of interest such as generalizability of ATACH-II results, clinical interpretation and implementation of results, further analysis, and publications. Also discussed were AHA/ASA guidelines in the context of ATACH-II results.

Finally, thanks to everyone who participated in the ATACH-II Clinical Trial. My sincere gratitude to each one of you for your hard work, commitment, effort and collaboration in making the trial a success!

I hope you all are enjoying the remaining summer days. And I wish you all the best with future endeavors.

Warm regards,

Adnan I. Qureshi, M.D.

Inside this Issue...

Clinical Coordinating Center
Zeenat Qureshi Stroke Research Center
University of Minnesota
www.atach2.com

UNIVERSITY OF MINNESOTA

ATACH-II Awards: Outstanding Performance in Enrollment

This award was given to the top 10 enrolling sites. These sites have also achieved a retention rate above 90% for all subjects that they enrolled, and have shown good overall compliance to the study protocol.

National Cerebral and Cardiovascular Center, Japan: Enrolled 79 Subjects
Retention Rate = 100%

Beijing Tiantan Hospital, China: Enrolled 72 Subjects
Retention Rate = 100%

Kobe City Medical Center General Hospital, Japan: Enrolled 53 Subjects
Retention Rate = 100%

Toranomon Hospital, Japan: Enrolled 38 Subjects
Retention Rate = 97.4 %

The First People's Hospital in Taizhou, China: Enrolled 37 Subjects
Retention Rate = 100%

National Taiwan University Hospital in Taipei, Taiwan: Enrolled 36 Subjects
Retention Rate = 100%

Columbia University Hospitals in New York, USA: Enrolled 27 Subjects
Retention Rate = 92.6%

St. Cloud Hospital in Minnesota, USA: Enrolled 26 Subjects
Retention Rate = 92.3%

Abington Memorial Hospital in Pennsylvania, USA : Enrolled 23 Subjects
Retention Rate = 95.7%

Baylor College of Medicine in Texas, USA: Enrolled 20 Subjects
Retention Rate = 100%

ATACH-II Awards: Overall Efficiency and Quality

Overall efficiency and quality, as defined by "enrollment per 90 days" efficiency above the expected standard **plus** excellence in data entry **and** query (or "DCR") response, **and** overall protocol compliance, but without quite meeting the criteria for the "top 10" award.

1.

- **University Hospital Heidelberg**
- **Enrolled 14 Subjects**

2.

- **The University of Texas Medical Center Houston NETT hub,** with recognition for spoke hospital **Memorial Hermann Texas Medical Center** (11 subjects), and also **Tulane Medical Center** (4 subjects), **University Medical Center, Brackenridge** (3 subjects) and **Seton Medical Center, Austin** (1 subject).

ATACH-II Clinical Trial Partners

The ATACH-II trial is managed and conducted locally through collaboration with the following groups and we greatly appreciate their contribution:

United States: Neurological Emergencies Treatment Trials [NETT] network at the University of Michigan,

Japan: National Cardiovascular Center [NCVC] and Japan Cardiovascular Research Foundation,

China: Beijing Tiantan Hospital and Shanghai SLG CRO Co., Ltd.,

Taiwan: China Medical University Hospital-Clinical Trial Center of Excellence,

Germany: Coordination Centre for Clinical Trials [KKS] at University Hospital Heidelberg, and

South Korea: Symyoo and Seoul National University Hospital [SNUH].

ATACH-II Clinical Trial Publications

The primary results of the ATACH-II clinical trial published in The New England Journal of Medicine is available on the following link: http://www.nejm.org/doi/full/10.1056/NEJMoa1603460#t=article

ARTICLE METRICS

Article metrics as of August 5, 2016: (Article metrics offer valuable insight into an article's global impact and collective reach).

Page Views: **107,213**
Media Coverage: 12
Social Media: Ranks 254th

Compared to Other NEJM Articles
ATACH-II article is in the **98**th Percentile

Compared to Articles in Other Medical Journals
ATACH-II article is in the **99**th Percentile

A note about acknowledgements:

A comprehensive acknowledgement list of everyone who contributed to ATACH-II success is being published online. Our goal is to acknowledge the work of all sites and all team members on this list. The comprehensive list has not yet been made public but people will be able to access the link from our atach2.com website soon. Please visit the list to check your name and site information as soon as you can, and encourage your team members to do so also at: ATACH-II Acknowledgement List

Please also email adnaniqureshi.a2publications@gmail.com or Kathryn France (kafrance@umn.edu) with any questions, concerns, comments, and your confirmations for your name on the acknowledgement list if you have not already done this. The online list will continue to be updated as these come in. Thank you!

A note about publications:

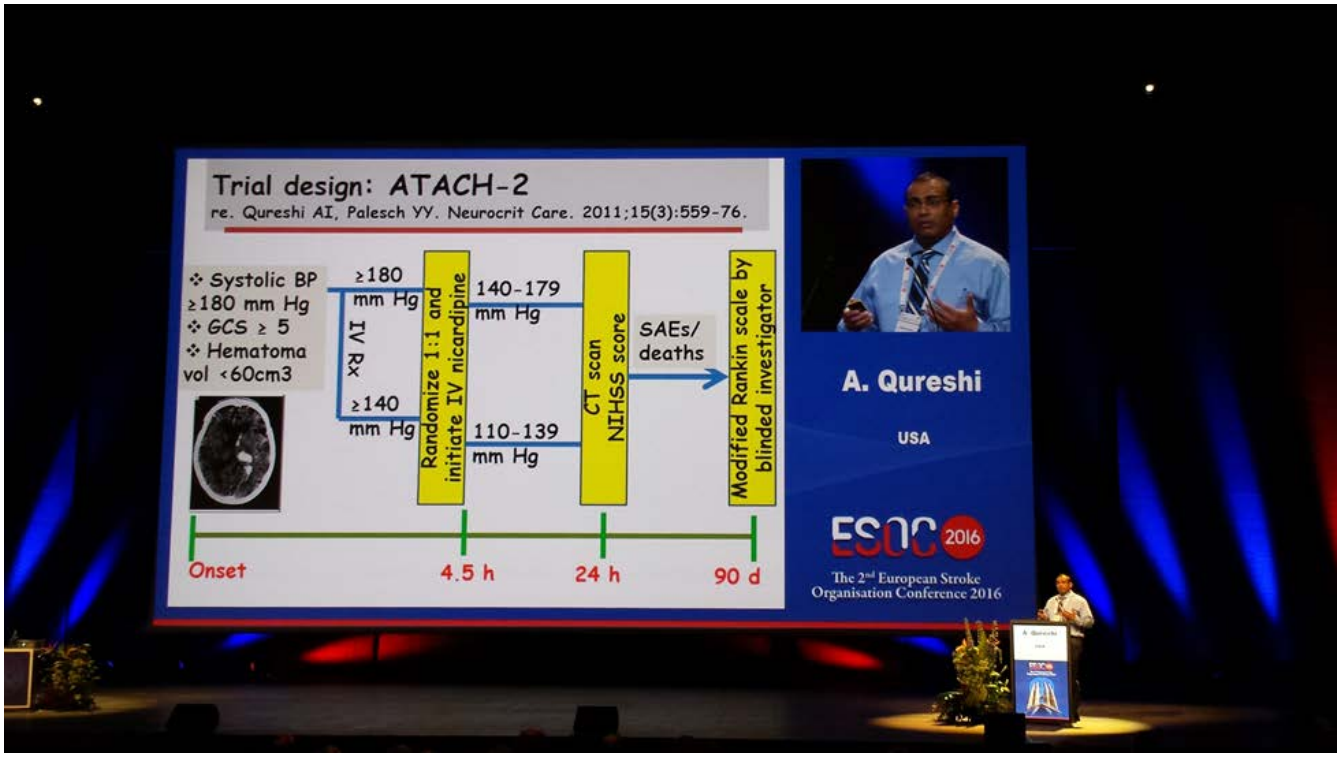
We encourage any ATACH-II investigators who have ideas for publication to submit these as soon as possible. The official ATACH-II Publications policy is posted in "Project Documents" in WebDCU. Essentially, all proposals should be submitted to the ATACH-II Publications Committee via copy to the following four emails in order to have it prioritized appropriately for committee review and statistical assistance:
Lydia Foster, email: fosterl@musc.edu, Yuko Palesch, email: paleschy@musc.edu, Adnan Qureshi, email: qureshai@gmail.com and Jessy Thomas, email: thoma098@umn.edu .
A format template and submission checklists are also available.

ATACH-II 2016 Investigators' Meeting Pictures

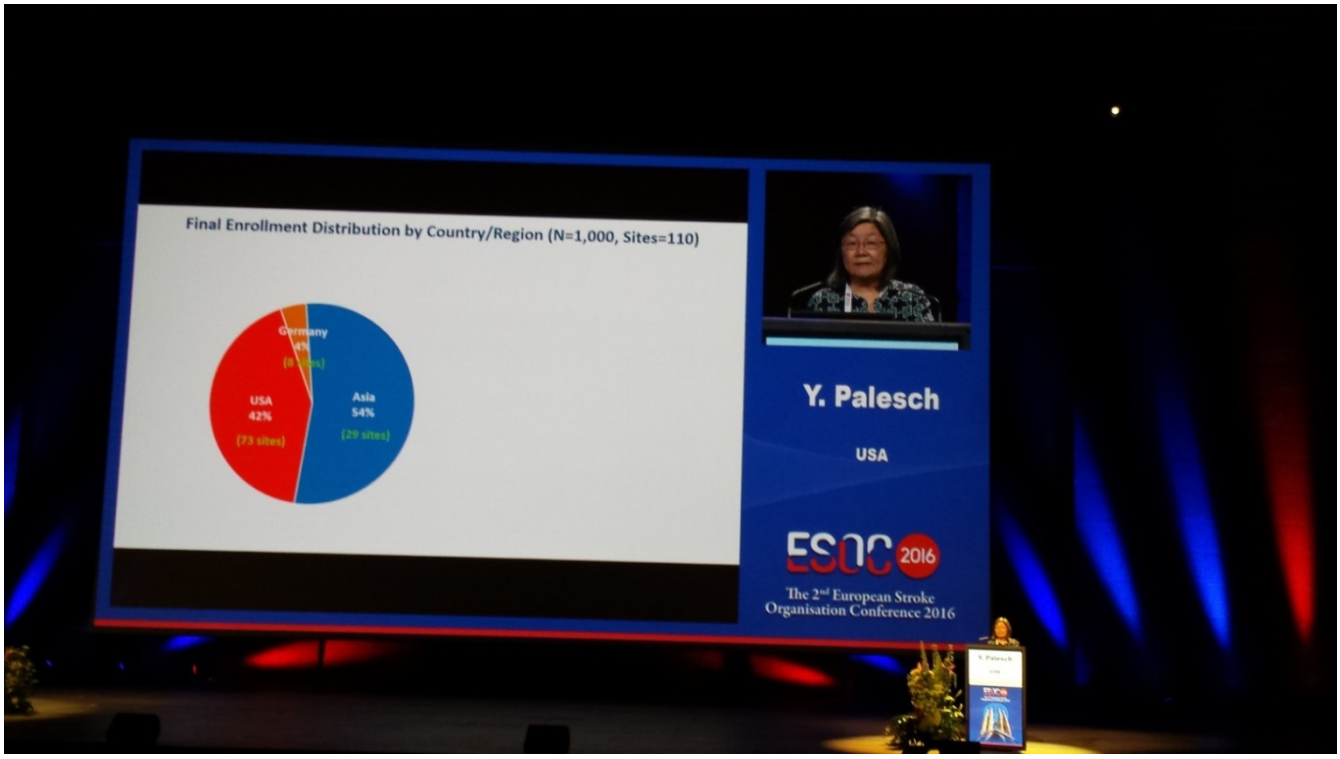
The Final Investigators' Meeting pictures are available on the atach2 website at the following link: http://atach2.com/investigators-meeting-2016/

European Stroke Organisation Conference 2016 (ESOC)

ESOC 2016 – Prof. Urs Fischer Interviews Prof. Adnan Qureshi about ATACH-II Results:
https://youtu.be/bEG_c5q71sU



Dr. Qureshi and Dr. Palesch Presenting Primary Results from ATACH-II at ESOC-2016



Final ATACH-II Trial Site Leaderboard –Top 10 Sites in Enrollment

Rank	Site Name	Country	No.	Principal Investigator(s)	Primary Study Coordinator
1	National Cerebral and Cardiovascular Center	Japan	79	Toyoda, Kazunori	Hirase, Kanae
2	Beijing Tiantan Hospital	China	72	Wang, Yongjun	Ding, Zeyu
3	Kobe City Medical Center General Hospital	Japan	53	Sakai, Nobuyuki	Okitsu, Miyuki
4	Toranomon Hospital	Japan	38	Hara, Takayuki	Matsukami, Mihoko
5	The First People's Hospital of Taizhou	China	37	Wang, Zhimin	Chen, Jie
6	National Taiwan University Hospital	Taiwan	36	Jeng, Jiann-Shing	Wang, Yu-Ting
7	Columbia University	USA	27	Agarwal, Sachin & Lee, Kiwon	Falo, Cristina
8	St. Cloud Hospital	USA	26	Suri, M. Fareed K	Freese, Melissa
9	Abington Memorial Hospital	USA	23	Shah, Qaisar	Jonczak, Karin
10	Baylor College of Medicine	USA	20	Suarez, Jose & Sergot, Paulina	Calvillo, Eusebia & Keene, Kelly

Final ATACH-II Trial Country Leaderboard

Rank	Country	Number of Subjects Enrolled	Number of Sites that Enrolled
1	United States	422	73
2	Japan	288	14
3	China	137	5
4	Taiwan	95	8
5	Germany	41	8
6	South Korea	17	2
	Total	**1,000**	**110**

Recent DSMB Meetings

September 14, 2015
Based on interim analysis of efficacy and futility on the first 850 enrolled subjects, the DSMB decided that the trial was unlikely to demonstrate a difference in outcomes between the two treatment groups even if it were to complete enrollment of the planned 1280 subjects. Therefore, further enrollment of new subjects in this trial was suspended, while other aspects of the trial were required to be continued as planned. The study was not stopped because of any safety concerns. NINDS concurred with the DSMB's decision.

February 23, 2015
The DSMB found everything to be satisfactory and recommended that the study proceed as planned.

May 6, 2014
DSMB had no safety concerns and recommended that the study continue as planned.

November 1, 2013
The DSMB recommended to NINDS that Clevidipine not be allowed as an alternative to Nicardipine for the ATACH-II trial.

October 6, 2013
DSMB had no safety concerns and recommended the study continue.

April 22, 2013
DSMB reviewed the safety and overall progress of the trial: found everything to be satisfactory and recommended the study proceed as planned.

Site Close-Out Check-List

Site Close-Out Check-List

Funded by: NINDS/NIH Site Name:

The purpose of this document is to help facilitate the site close-out process. You can keep the completed Check List at your site with the rest of the study documents.

Site Requirements	✓	Comment	Resp. Group
1. Dispose or use the remaining study drug per local guidelines and document accordingly.	☐		CRO/Site
2. Send any outstanding additional images to UMN (**Optional**) -These are images that you have listed in WebDCU as available to be sent to UMN	☐		CRO/Site
3. Ensure all payments have been received	☐		CRO/Site
4. Submit any required/applicable regulatory documents (to IRB/ EC, CA etc.)	☐		UMN/CRO/Site
5. Secure Subject ID code list (Master subject log) and signed consent forms at site.	☐		CRO/Site
6. Update the Delegation of Authority log and upload it in the ATACH-II database/WebDCU under **Delegation of Authority Log**. a. Add end dates for all team members b. PI sign and date at the end of the document	☐		CRO/Site
7. Upload documentation of IRB approval of final study closure in the ATACH-II Database/WebDCU under: **IRB Close-out Acknowledgement**.	☐		CRO/Site
8. Change the status of Study Team Members to **inactive** in the **Site Team Member table**.	☐		CRO/Site
9. **Data retention requirements:** -NIH requires data retention for three years -HIPAA related documents must be retained for 6 years (US) -Follow federal/local requirements if longer retention is required.	☐		NETT/UMN/ CRO/Site

10. ***The National Institutes of Health (NIH) requires that all investigators who are funded by NIH must submit an electronic version of their final, peer-reviewed manuscript to PubMed Central upon acceptance for publication, no later than 12 months after the official date of publication.***

PI Name: _____ Date: _____

Signature: _____

Contact Information for ATACH-II

Don't hesitate to reach out to us with any ATACH-II questions!

Contract or Reimbursement Questions? Contact Norrita Rech at 612-626-1866 or rech@umn.edu

Clinical or Study Drug Questions? Contact Kathy France at 763-229-3821 or kafrance@umn.edu

General Questions? Contact Jessy Thomas at 612-624-2431 or thoma098@umn.edu

WebDCU Questions? Contact Catherine Dillon at 843-876-1942 or rileycp@musc.edu

NETT CCC Questions? Contact 734-232-2142 **or** ATACHII-TRIAL@UMICH.EDU

UNIVERSITY OF MINNESOTA

Clinical Coordinating Center
Zeenat Qureshi Stroke Research Center
University of Minnesota
925 Delaware Street SE Suite 300
Minneapolis, MN 55414
Phone: (612) 625-6974 | Fax: (612) 301-9292

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA

Statistical and Data Coordinating Center
Medical University of South Carolina
Data Coordination Unit
Department of Public Health Sciences
135 Cannon Street, Suite 303
MSC 835 Charleston, SC 29425-8350
Phone: (843) 876-1919 | Fax: (843) 876-1923

Funded by NIH through grants U01NS062091 and R01NS061861; The content is solely the responsibility of the authors and does not necessarily represent the official views of NINDS or NIH.