

IHAST2 Update

March 2003, Volume 4, No. 1

Inside

page

<i>Timeline for Completion of IHAST2</i>	1
<i>Closeout</i>	2
<i>Patient Notification</i>	2
<i>Publication</i>	3
<i>Data Completion Reminders</i>	3

Timeline for Completion of IHAST2

At the time of this writing, only 12 more patients remain to be randomized into IHAST2. It has been a very long road - but we are finally nearing the completion of an extraordinary project. Again, I want to thank each and every one of you for making this possible!

Enrollment of the last patient **DOES NOT** mean that everything is finished however. In fact, we have a lot of work to do over the next 6-9 months to complete our data-gathering effort, complete final audits, and identify, send and manage all the inevitable data edits, etc. At the time of the October 2002 Annual Meeting in Orlando, we reviewed a suggested timeline for completion of IHAST2. We've continued working on this process. Nothing is "absolutely, unquestionably, final" - but I think we have a pretty good idea of our activities over the next year.

April 5, 2003:

Approximate date the last patient will be randomized into IHAST2. An email dated March 17, 2003 was sent detailing how we will handle the last patient.

August 5, 2003:

Final patient follow-ups are completed

Comment: It will be very important to finish follow-up of these last patients in a timely fashion. Delays in getting the data completed mean delays in data analysis and delays in reporting the results.

September 1, 2003:

Last CRFs received at the DMC

September 15, 2003:

Last on-site audit completed

October 11, 2003:

IHAST2/CFAAST Annual Meeting
San Francisco, California

November 15, 2003:

All DERs generated

December 15, 2003:

All DERs resolved

January 1, 2004:

Database Closed

February 2004:

Final Investigators' Meeting
San Diego, California*

Trial results will be presented to investigators.

**Comment: I had originally told everyone that we would present trial results at our October meeting (in San Francisco). However, the DSMB does not want us to present results prior to completion and "freezing" of the database. We can't get that done before October - so instead we've decided to have our final investigators' meeting in conjunction with the Stroke Meeting February 5-7, 2004. We have a LOT of planning to do and we aren't sure how to pay for both meetings. More information will follow later.*

Please File Your IHAST2 Updates

Please file one copy of each edition of the *IHAST2 Update* in your Site Regulatory Binder. (See Chapter VII.A.5 of the Operations Manual)

Closeout

Even though the last patient is knocking on the IHAST2 door, there is still much to be done. There are a few really important items associated with the closeout of IHAST2 that we want to bring to your attention:

IRB Approval must be maintained until all of the following occur:

- Final patient enrolled at your center has had their 3-month follow-up
- Closeout audit is completed
- Final corrections are completed
- Any outstanding DERs or data queries have been resolved

All data must be submitted before we can freeze the database to do the analysis. We anticipate that this will occur roughly around January 2004. You will receive verification by email when all the data from your center is complete.

Once you have received verification that there are no outstanding data issues, you will need to submit a "project closure" notification form to your IRB letting them know that this clinical trial is over.

Archive Information Form Completion & Submission

If you have not already received and completed the "IHAST2 Archiving Information Form", please complete one now. A copy of the form is attached to this newsletter. The archiving form identifies a contact person, the complete mailing address for each center and the storage location for the IHAST2 materials once the study is over. This form also identifies a contact person to facilitate the return of the PolarAir units to Augustine Medical. A completed form should be stored in the IHAST2 Regulatory Binder at your site, and another copy

should be faxed to the CCC at: 319-384-8072. We also suggest giving a copy of the completed form to the PI and Co-PI.

Patient Notification

We've been asked by several of you - and by the DMSB - regarding notifying patients about the results of the trial. This is the responsibility of local centers. As you know, we don't have the patients' names, addresses, phone numbers, etc. Also, different local IRBs may have different rules.

Sometime around the time that our primary outcome paper is scheduled to appear in print, we will send each center a draft letter that could be modified and sent to your local patients, and a draft press-release if you are either contacted by or wish to contact your local media. We believe that before sending letters to patients, you should seek the approval of your local IRB.

There is one other issue. When the results are released, it is possible that some patients may call and want to know "what group was I in". Since IHAST2 does not involve "ongoing therapy", information regarding group assignment does not have any influence regarding patient well-being. Neither we nor the DSMB feels that it is necessary to specifically notify each patient of their group assignment. HOWEVER, we also agree that this information should not be DENIED to any patient who asks. Our plan, in mid 2004 (at the time we send out the draft letter and press-release) will be to provide each center with a summary of PID and the actual temperatures recorded at the time clipping for each patient. This should make it easier for you to provide information to those patients who ask.

Publication

The Web site for submitting data requests is up and operating. We've only received one request - but there's lots of time. I want to clarify a few points.

- a) We are still "pushing" to get as many requests before we freeze the database and release the primary results. Getting questions defined "in advance" is preferable to questions asked after the results are known.
- b) It will be much easier to "process" questions submitted in the near future - simply because we won't be tied up doing the data analysis.
- c) Remember - we can process a question, but we can't provide ANY DATA until after the database is closed and until AFTER the results have been provided to the investigators.
- d) Even after data is provided, investigators will need to submit their manuscripts for approval, and no secondary analysis will be submitted for publication until the PRIMARY paper has been accepted for publication. In essence, the earliest you can think about submitting manuscripts based on data requests is mid-2004.

Data Completion Reminders

Following are a few last minute reminders about completing and submitting data forms:

- If you expect a patient to be hospitalized much beyond the "usual" 14 days (and hence expect forms submission to be delayed), be certain to contact Kaye Eisele at the Data Management Center.
- Review completed DERs or data corrections requested by email carefully before FAXing.

Please indicate if you are intentionally sending a partial DER.

- Remember to date and initial all corrections.
- Please remember to fill in the Center ID # and Log # in the header of all SCREENING and ELIGIBILITY forms.
- On occasion, we receive multiple copies of the same DER and CRFs. If you are uncertain as to whether the DMC has already received this data, please contact Kaye.
- As you know, Weekly Patient Summary Reports are emailed to centers each Monday morning. By attending to these outstanding items and submitting requested data before 3 pm that Friday, they will not show up on the following Monday Report.
- Once you are notified by email that the last patient has been randomized, please mail to the DMC all SCREENING and ELIGIBILITY forms completed for the "non-enrolled" patients.

As mentioned earlier in this Newsletter, getting all of data "cleaned up" and into the database in a timely fashion is a critical part of completing the study. Unresolved DERs or missing data means we can't close the database - which means we can't analyze the data. This means we (mostly Kaye) will almost certainly be bugging you as we move through 2003.

T*H*A*N*K*Y*O*U