

## TEMPO-2 Site Start-Up Guide

Prior to site activation we require some start-up Study Documents and Training Certificates for all delegated study staff. This document will walk you through the completion of these start up tasks and direct you to resources you may find helpful.

### Regulatory Binder:

Please provide the following regulatory and training documents for your site and all delegated study staff:

#### 1) Individual Training Documents:

- mRS (Modified Rankin Scale) Certification
- NIHSS Certification
- TEMPO-2 Specific Training Video Certifications:
  1. tNK Reconstitution and Administration
  2. Obtaining Informed Consent
  3. iDatafax (database) training

Training videos can be accessed at:

<http://ucalgary.ca/dcns/research/tempo-2/tempo-2-videos>

*Select "Cancel UofC Access login"*

*Then enter:*

*User Name: TEMPO2*

*Password: Stroke33*

*When finished, click the "COMPLETION CERTIFICATE" button for each "Consent & TNK Administration" and "iDatafax Training"*

- Good Clinical Practice (GCP) Certification
- Current Health Professional License
- Signed and dated CV

#### 2) Site Level Regulatory Documents

- Executed Clinical Trial Agreement
- Local Ethics Approval (relative amendments/correspondence)
- Approved Patient Consent Form/ Surrogate (if applicable)
- Signed Protocol Acceptance Letter
- Local Lab Accreditation
- Local Lab Normals/ Accepted Values
- Ethics Membership List
- Clinical Trial Site Information Form (Canada only)
- Qualified Investigator Undertaking Form (Canada only)



### Study Documents:

The following documents will be sent to you via email:

- DOA- Delegation of Authority log
- Staff Training Log (please complete at SIV)
- Protocol Acceptance Signature Page
- Subject Enrollment Log
- Monitoring Log
- CRF Source - Word and PDF (please use this as Source)
- TEMPO2 Enrollment Checklist (optional to use and please amend as per your site)
- CRF Completion Instructions
- TEMPO2 Consent labels
- Dosing Labels for CRF (suggest use of bright colored labels)
- Day 90 Blinded Attestation Form

These documents, along with other resources for TEMPO-2, are also available on the study website:

<https://www.ucalgary.ca/dcns/research/tempo-2/tempo-2-documents>

Select "Cancel UofC Access login"

Then enter - User Name: TEMPO2/ Password: Stroke33

### TEMPO-2 Randomizer/ Study Manager:

- ❖ <http://tempo2.cru.ucalgary.ca/>
- ❖ Please email Carol Kenney ([ckenny@ucalgary.ca](mailto:ckenny@ucalgary.ca)) to request randomization access for members of your team who will be randomizing. TNK Administration Training certificates must be completed prior to receiving randomization access.
- ❖ All of the above listed required Regulatory Documents must be uploaded to Study Manager. You may request Manager access to maintain your site's files or Johanna Delongchamp can assist your site with uploading your Regulatory Documents. Email: [jmzaalde@ucalgary.ca](mailto:jmzaalde@ucalgary.ca)

### iDatafax (Database):

- ❖ iDatafax Training certificates must be completed prior to receiving database access. Please email Carol Kenney ([ckenny@ucalgary.ca](mailto:ckenny@ucalgary.ca)) to request database access for those members of your team responsible for data entry.
- ❖ PI's are required to have access for Electronic Sign Off (3 places) in the database.
- ❖ The CRU (Clinical Research Unit) at the University of Calgary manages the database. Qiao Zhang is the Project Manager for TEMPO-2. Email: [qiao.zhang@ucalgary.ca](mailto:qiao.zhang@ucalgary.ca)

### Imaging Transfer:

- ❖ Marina Salluzzi is the manager of the CPAC Central Imaging for TEMPO2. She will contact you to set up electronic transfer of images to the University of Calgary. Email: [msalluzz@ucalgary.ca](mailto:msalluzz@ucalgary.ca).

### Contract:

- ❖ Michelle Wright is the Finance and Contract Manager for TEMPO2. Email: [mwright@ucalgary.ca](mailto:mwright@ucalgary.ca)



Should you have any questions regarding the above list, please don't hesitate to contact us at the TEMPO-2 Coordinating Centre at [TEMPO2@ucalgary.ca](mailto:TEMPO2@ucalgary.ca). We look forward to your collaboration and contributions to this international trial.

<b>TEMPO-2 Coordinating Centre, University of Calgary Site Information</b>			
Address: Room C1241B- 1403 29 Street NW, Foothills Medical Centre			
City: Calgary	Prov: AB	Postal: T2N2T9	Country: Canada
Preferred E-mail for data query reports: <a href="mailto:ckenney@ucalgary.ca">ckenney@ucalgary.ca</a>			

<b>Site Principal Investigator</b>	<b>Site Co. Investigator</b>
Prefix: Dr. First Name: Shelagh Last Name: Coutts E-mail: <a href="mailto:scoutts@ucalgary.ca">scoutts@ucalgary.ca</a> Phone: 1 403-944-1594 Mobile: 1 403-619-5986 Fax: 1 403-270-4269	Prefix: Dr. First Name: Michael Last Name: Hill E-mail: <a href="mailto:michael.hill@ucalgary.ca">michael.hill@ucalgary.ca</a> Phone: 1 403-210-7786 Mobile: 1 403-862-2837

<b>Lead Coordinator</b>	<b>Finance and Contracts Manager</b>
Prefix: RN First Name: Carol Last Name: Kenney E-mail: <a href="mailto:ckenney@ucalgary.ca">ckenney@ucalgary.ca</a> Phone: 1 403-944-4286 Mobile: 1 403-714-0659 Fax: 1 403-270-4269	First Name: Michelle Last Name: Wright E-mail: <a href="mailto:mwrigh@ucalgary.ca">mwrigh@ucalgary.ca</a> Phone: 1 403-210-8676 Mobile: 1 587-437-9163 Fax: 1 403-270-4269

<b>Project Coordinator</b>	<b>Imaging Manager</b>
First Name: Johanna Last Name: DeLongchamp E-mail: <a href="mailto:jmzaalde@ucalgary.ca">jmzaalde@ucalgary.ca</a> Phone: 1 403-210-9322 Fax: 1 403-270-4269	First Name: Marina Last Name: Salluzzi E-mail: <a href="mailto:msalluzz@ucalgary.ca">msalluzz@ucalgary.ca</a> Phone: 1 403-944-3632

<b>Clinical Research Unit, University of Calgary Project Manager (iDatafax)</b>	<b>United Kingdom Sponsor Contact</b>
First Name: Qiao Last Name: Zhang E-mail: <a href="mailto:qiao.zhang@ucalgary.ca">qiao.zhang@ucalgary.ca</a>	First Name: Alicia Last Name: Murray E-mail: <a href="mailto:Alicia.Murray@glasgow.ac.uk">Alicia.Murray@glasgow.ac.uk</a> Phone: + 0141 451 5903
<b>Australian Sponsor Contact</b>	<b>European Sponsor Contact</b>
First Name: Jessica Last Name: Tsoleridis E-mail: <a href="mailto:Jessica.Tsoleridis@mh.org.au">Jessica.Tsoleridis@mh.org.au</a> Phone: +61 3 9342 8443 Alternate phone: +61 3 9342 4424	First Name: Katrina Last Name: Tobin E-mail: <a href="mailto:katrina.tobin@ucd.ie">katrina.tobin@ucd.ie</a> Phone: +353 1 716 4576

