

# Interim Process for Study Visit Documentation

This interim process only applies to studies that are **NOT** in an “Active” state in Click CTMS..

Active

If a study is in an “Active” state, patients are logged in Click CTMS using the normal process.

## Navigate to the Study Summary Page

CRS00003006  
UA - Velocity - 16-6001 - Pershad - BUMCP

Submitted: 6/1/2017  
Approved: 8/3/2017  
IRB ID: 1703278830  
IRB Status: Approved  
IRB Approved: 3/16/2017  
IRB Expiration: 3/14/2018

Activities: History | Change Log | Regulatory 2 Overview | Clinical Extension | Chemistry | Version History | Reporting Tools | Agreement & Renotation | Regulatory Documents

Principal Investigator: Ashish Pershad | Current Address: |  
Primary Sponsor: Abbott Cardiovascular Systems Inc. | Green Failures: |  
Other Sponsors: On Study: | Off Study: |

Activities List:

Activity Name	Structure	Entity Activity	Status
Regulatory	Regulatory	Entity Activity	Open
Regulatory	Regulatory	Entity Activity	Open

Draft

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Edit Project  
Print Project

Next Steps

- Submit for CTO Pre-Review
- Withdraw
- Log Event or Milestone
- Log Public Comment**
- Copy Study

- Logging a study visit for the interim process is completed from the Study Summary page. The Study Summary page has the study title and study details.
- Confirm that the study is in a state other than “Active”. If a study is in an “Active” state, patients are logged in Click CTMS using the normal process.
- Select *Log Public Comment* from the **Next Steps** menu.

## Participant Logging – Public Comment

- In the **Comments** section list:
  - Patient Name
  - Patient DOB
  - Patient MRN (if available)
  - Visit Name
  - Visit Date
  - Any other applicable information about the visit
- In the **Attach Documents** section, you may use the *Add* button to attach any applicable documentation related to the visit. This is an optional step.
- Select *OK* to submit the public comment.

### Log Public Comment

ID: CRS00003006  
Title: UA - Velocity - 16-6001 - Pershad - BUMCP  
Principal Investigator: Ashish Pershad  
Primary Sponsor: Abbott Cardiovascular Systems Inc.

Execution of this activity will log a comment visible to everybody with access to the study workspace.

- Provide comments in the box below.
- Select “OK” to mark the study as completed.
- Select “Cancel” to return to the study workspace without taking action.

\* Comments:

Patient Name, DOB, MRN (if available), Visit Name, Visit Date

Any other applicable information regarding the visit.

Attach Documents:

Add

Name	Version Number
Any Applicable Documentation.pdf	0.01

Upload Revision | Delete

OK Cancel

This interim process is only a temporary solution for ensuring billing compliance before a study is activated in Click CTMS.

Study coordinators, with the exception of coordinators working on a UA study, will be responsible logging past visits once a study is “Active” in Click CTMS.