

Public reporting burden for this collection of information is estimated to average 27 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (OMB#0925-0753). Do not return the completed form to this address.

| | | | | | |
|------------------------------|-----------------|------------------------------|------------|------------------------|------------------|
| Credited Group | ECOG-ACRIN | Auditing Group | ECOG-ACRIN | Audit Type | Routine audit |
| Institution Name | Yale University | Institution CTEP Code | CT018 | Tier | TIER2 |
| Membership Study Type | Treatment | Audit Category | Treatment | Membership Type | LAP5 main member |
| Audit Date | 09/20/2017 | | | | |

| List of Followup | | | | Update Follow-up Items | |
|---------------------------------|--------------|----------------|----------------------------|--------------------------------|--------------------|
| Follow-up Item | Requested By | Date Requested | Date Response sent to CTMB | Follow-up Item | IRB deficiency |
| IRB deficiency | Group | 10/02/2017 | | Requested by Group | |
| Informed consent content | Group | 10/02/2017 | | Date Requested | 10/02/2017 |
| Pharmacy | Group | 10/02/2017 | | Date Due to CTMB | 11/16/2017 |
| Informed consent | Group | 10/02/2017 | | CTMB External Comments | |
| Eligibility | Group | 10/02/2017 | | Group Comments for CTMB | FUP Required |
| Treatment | Group | 10/02/2017 | | GROUP Internal Comments | |
| Disease outcome/response | Group | 10/02/2017 | | Date Request sent to PI | |
| Adverse Events | Group | 10/02/2017 | | Date Response due from PI | |
| General data management quality | Group | 10/02/2017 | | Request sent to | |
| | | | | Date Response received from PI | |
| | | | | Date Response sent to CTMB | |
| | | | | Date Received by CTMB | |
| | | | | Follow-up Status | Pending |
| | | | | Follow-ups | Upload/Attachments |
| | | | | | Save Clear |

| | | | | | |
|------------------------------|---|------------------------------|------------|------------------------|--------------------|
| Credited Group | ECOG-ACRIN | Auditing Group | ECOG-ACRIN | Audit Type | Initial |
| Institution Name | John H Stroger Jr Hospital of Cook County | Institution CTEP Code | IL042 | Tier | TIER2 |
| Membership Study Type | S1400 | Audit Category | Treatment | Membership Type | NCORP MU component |
| Audit Date | 10/20/2017 | | | | |

| File Category | File Sub Category | File | Accessible To | Comments | Uploaded By | Uploaded Date |
|----------------------------|-------------------|------|---------------|----------|-------------|---------------|
| No data available in table | | | | | | |

| Audit Date (MM/DD/YYYY) | Audit Category | View/Upload Files |
|-------------------------|----------------|-----------------------------|
| 11/17/2017 | Treatment | View/Upload |
| 10/20/2017 | Treatment | View/Upload |
| 10/13/2017 | Treatment | View/Upload |
| 09/20/2017 | Treatment | View/Upload |
| 09/14/2017 | Treatment | View/Upload |
| 09/06/2017 | Treatment | View/Upload |
| 08/24/2017 | Treatment | View/Upload |
| 08/17/2017 | Treatment | View/Upload |
| 08/14/2017 | Prevention | View/Upload |
| 07/25/2017 | Treatment | View/Upload |

July 2018

CTIS INC.,