

# Maximizing Clinical Trial Operations: Pharmacy Perspective

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# What defines an ideal clinical trial site?

**There is no absolute ideal**

Each site has its unique strengths and weaknesses when it comes to patient randomization.

# Examples of weaknesses and strengths

## Weaknesses:

Limited resources  
Inadequate training  
Protocol deviations  
Patient recruitment challenges

Modifiable vs  
non-  
Modifiable

## Strengths:

Experience  
Infrastructure  
Compliance  
Dedicated staff

Strength =  
Communication!!  
!

## Epidemiological chronorisk of stroke

P. Pasqualetti, G. Natali, R. Casale, D. Colantonio

First published: January 1990 | <https://doi.org/10.1111/j.1600-0404.1990.tb00933.x> | Citations: 49

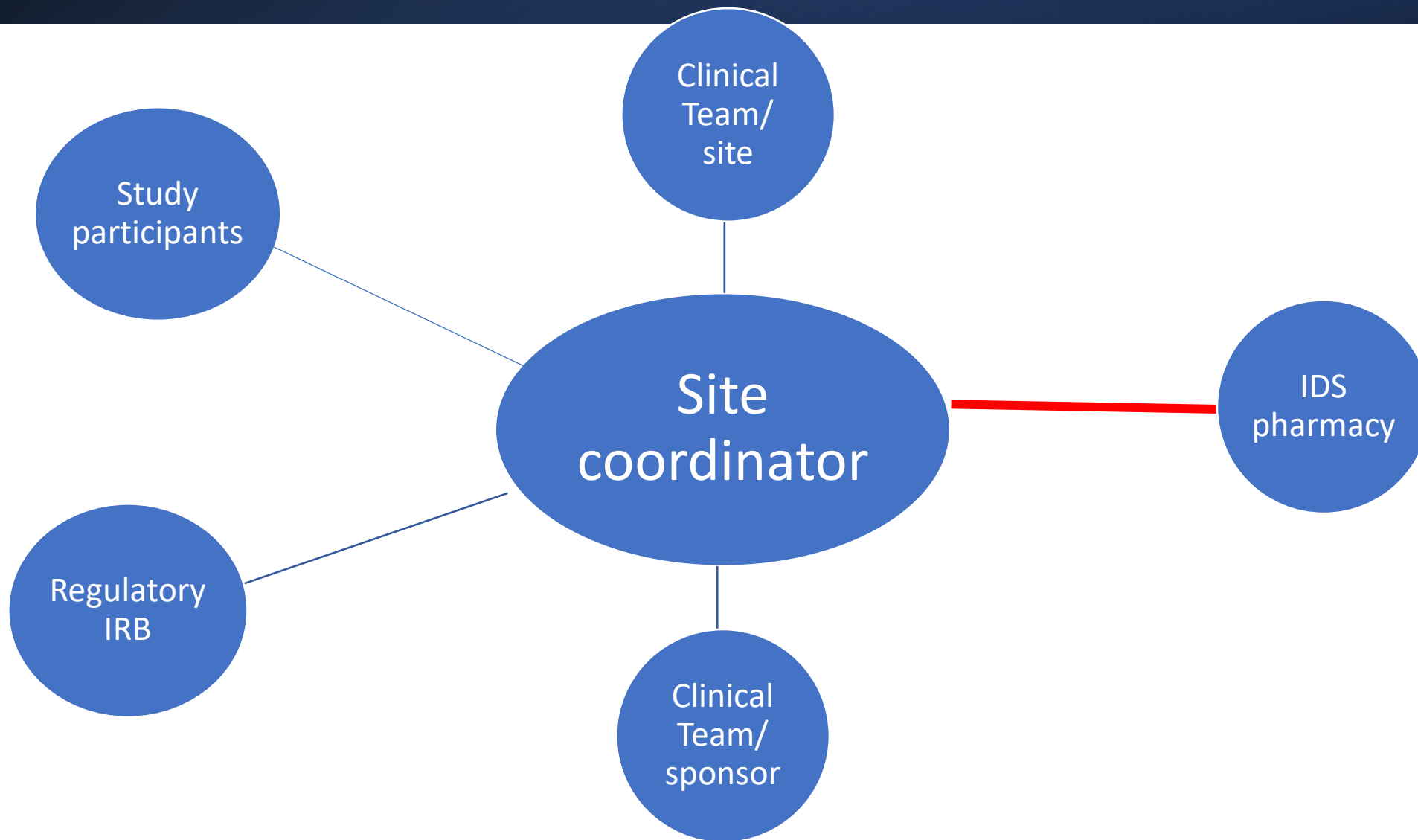
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### Abstract

A retrospective study was undertaken on onset of symptoms in 667 cases of stroke. All strokes occurred out of hospital. There were 382 males and 285 females, observed from 1971-1988. The 667 cases of stroke consisted of 508 cases of cerebral infarction and 159 cases of cerebral hemorrhage. The data, analyzed by the single cosinor method, demonstrate a significant circadian, circaseptan, and circannual rhythmicity in the occurrence of stroke. **The peaks occur in the morning hours, in the weekend, and in winter.** Cerebral hemorrhages do not have a circadian rhythmicity in their occurrence, while they do present circaseptan and circannual rhythmicity. Cerebral infarctions present circadian, circaseptan, and circannual rhythmicity. No difference was found between the circadian rhythmicity of cerebral infarctions and cerebral hemorrhages. The circannual distribution of stroke is similar to that of cerebral infarctions. The circaseptan distribution of stroke is similar to that of cerebral hemorrhages. Further understanding of the

**Employee Turnover is Highest in January:** How to Keep Critical Employees from Leaving

# Collaborative efforts



# Site-Pharmacy Role In clinical Trials

- Before Site Activation
- After Site Activation / Patient Enrollment

# Pharmacy role Before Site Activation



REVIEW FEASIBILITY  
QUESTIONER , PROTOCOL AND  
PHARMACY MANUAL



DETERMINE IF STUDY WILL  
PROVIDE ALL MEDICATIONS  
AND EQUIPMENT



PREPARE FOR SITE INITIATION  
VISIT / INTERNAL START-UP  
MEETING  
(E.G MOCK ENROLLMENT)



EDUCATE RESEARCH STAFF ON  
NEW STUDY MEDICATIONS



SET UP PHARMACY  
DISPENSING DATABASE AND  
EPIC PRESCRIPTIONS

# Pharmacy Role After Site Activation / Patient Enrollment



Manage study drug  
(accountability)

- Monthly inventory
- Temp excursion reporting
- Destroy or return if expired or unusable



Determine patient's  
treatment arm:  
medications to dispense (  
SISTER trial)



Request prescription to be  
signed by physician who is  
on FDA 1572 / DOA



Renew prescription as  
required by law

# Pharmacy Workflow

## After Site Activation / Patient Enrollment



Counsel patient about medication when dispensed



Ensure bottles are brought back at subsequent visits

### October 2023 DSMB Review: Medication Compliance

StrokeNet Data and Safety Monitoring Board II October 30, 2023

- Recommending diligent central **oversight of compliance rates** to ensure study integrity
- **Identify and address missing data** for medication adherence

relevant published safety outcomes in patients treated with these or similar anti-thrombotic regimens at our next joint meeting.

3. Future reports should include safety data with explicit boundaries indicating acceptable limits for major events. The SAP should be updated to include these boundaries.
4. Future reports should also include adjudicated and unadjudicated events, including adjudication dates, to help understand event throughput.
5. Please provide details on the adjudication process in subsequent meetings. E.g., who is adjudicating and where is it being done (central or not)?
6. We request that the unblinded statistician or medical safety monitor are available to attend closed sessions to provide insights into safety concerns and adjudication processes, if needed.
8. Monitor medication compliance closely, especially in cases where compliance rates are low, to ensure the study's integrity.
9. Address the problem of missing data in medication adherence and ensure that the data are entered correctly into the case report forms.
10. Prioritize integrating recruitment monitoring...
11. The DSMB will provide further input to the study team on the SAP utility analysis as soon as they are able to.

calibrations /  
certifications  
*Refrigerators, IV  
compounding hood*



# Pharmacist Role to improve Medication

## Adherence



Pharmaceutical Care & Health Systems

Research Article

### Safe and Effective Use of Medicines for Ethnic Minority Patients: A Reminders and Counseling Program That Improves Adherence

Pernille Dam\*, Mira El-Souri, Hanne Herborg, Lotte Stig Nørgaard, Charlotte Rossing, Morten Søgaard  
Danish College of Pharmacy Practice, Hillerød, Denmark

Abstract



Journal of the American Pharmacists Association

Volume 61, Issue 3, May-June 2021, Pages 340-350.e5



### Association of pharmacist counseling with adherence, 30-day readmission, and mortality: A systematic review and meta-analysis

CLINICAL STUDY

### Role of pharmacist counseling in medication adherence improvement

Sanii, Yalda<sup>1</sup>; Torkamandi, Hassan<sup>2</sup>; Gholami, Kheirabadi<sup>3</sup>

Author Information

Journal of Research in Pharmacy Practice 5(2):p 132-137

#### Findings:

There were significant differences in medication adherence and satisfaction between the study and control groups at the time of second follow-up. Medication adherence in the study group is 42.9% more than the control group, also the treatment satisfaction determined to be 33.5% more than patients in control group. Furthermore, we found that, in intervention group, no one is readmitted while among the control group eight people readmitted.

#### Conclusion:



Centers for Disease Control and Prevention  
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Division for Heart Disease and Stroke Prevention

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Programs

### Tailored Medication Counseling to Improve Medication Adherence

### Multifaceted Intervention to Improve Medication Adherence and Secondary Prevention Measures After Acute Coronary Syndrome Hospital Discharge

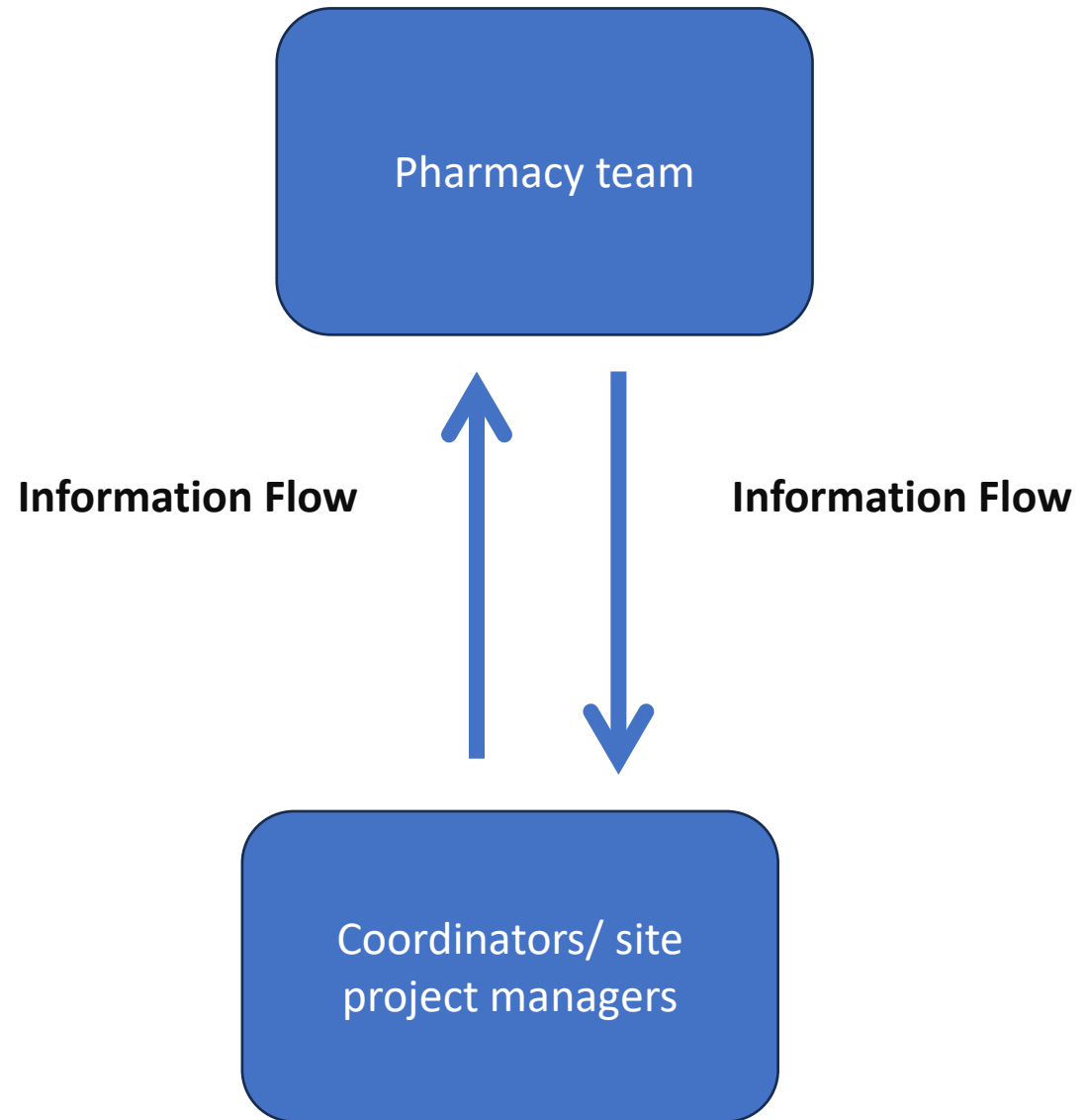
A Randomized Clinical Trial

**Interventions** The INT lasted for 1 year following discharge and comprised (1) pharmacist-led medication reconciliation and tailoring; (2) patient education; (3) collaborative care between pharmacist and a patient's primary care clinician and/or cardiologist; and (4) 2 types of voice messaging (educational and medication refill reminder calls).

**Results** Of 253 patients, 241 (95.3%) completed the study (122 in INT and 119 in UC). In the INT group, 89.3% of patients were adherent compared with 73.9% in the UC group ( $P = .003$ ). Mean PDC was higher in the INT group (0.94 vs 0.87;  $P < .001$ ). A greater proportion of intervention patients were adherent to clopidogrel (86.8% vs 70.7%;  $P = .03$ ), statins (93.2% vs 71.3%;  $P < .001$ ), and ACEI/ARB (93.1% vs 81.7%;  $P = .03$ ) but not  $\beta$ -blockers (88.1% vs 84.8%;  $P = .59$ ). There were no statistically significant differences in the proportion of patients who achieved BP and LDL-C level goals.

**Examples of an effective team communication:**

- ❖ Inform your pharmacy team upon identifying potential patients to allow them to review training materials and familiarize themselves with the procedures (e.g., in-patient pharmacy).
- ❖ Involve your team in reporting temperature excursions, as quarantined investigational products may temporarily halt enrollment at your site.
- ❖ If discrepancies are found during pill counts by some pharmacies, notify your coordinator for further action on non-adherence cases (subjects will require education and re-education).



# Announcement

New

## NIH StrokeNet Pharmacy Professional Committee (PPC)

Objective: Bring together pharmacists/ Pharmacy Technicians from different institutions involved in stroke care and research to collaborate, share best practices, and contribute to advancing stroke care.

A survey will be distributed soon, keep an eye out for an upcoming survey!

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