

MEETING SCIENTIFIC CHALLENGES IN INTERNATIONAL QUALITY OF LIFE STUDIES

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Introduction

LIDO (Longitudinal Investigation of Depression Outcomes) is an international observational study designed to assess the quality of life and economic correlates of recognized major clinical depression in primary care settings. It is being implemented in four phases: planning; recruitment; follow-up; and analysis.

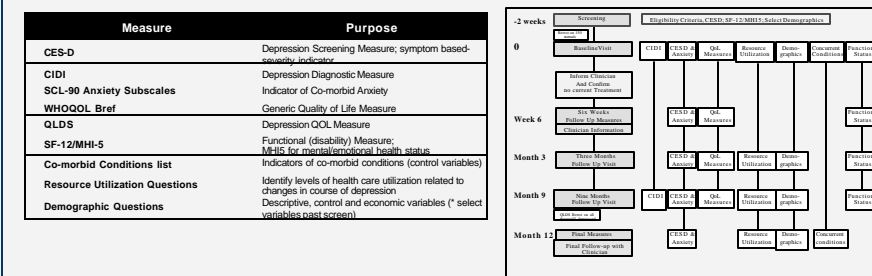


Common Protocols vs. Site Differences

Each site designed their study to meet the requirements in the LIDO Protocol. There were design features set by protocol requiring compliance across sites, and there were areas where each site could design the best methods for their settings.

Study Design

During the planning phase, the Research Team worked with study advisors and site investigators to design the study, select the measures and develop the international protocols.



Influencing Factors

A single international protocol was derived to support a single pooled international dataset. However, there are many country-specific factors that can introduce site-specific bias:

- Cultural differences (*news and stigma about depression differ*)
- Languages (*not all language versions of measures available / not all concepts easily translatable*)
- Health Care Systems (*differences in structural use and referral, as well as professional used*)
- Political/Economical (*countries at unrest, economies failing*)
- Natural History (*strong active immigration patterns, war, terrorism, bank freezes, seasonal changes*)

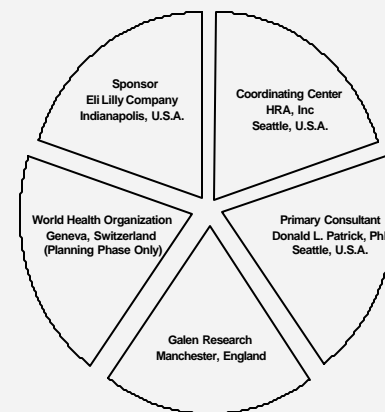
What could change by sites

- selection of primary care sites
- selection of institution affiliation
- staffing designs
- patient compliance (retention plans)
- ethic committee process
- letters to doctors and patients
- activities to maintain clinic sites

Common protocol compliance required

- measures and study forms
- measure periodicity and timing windows
- orientation process
- CIDI training + monitoring
- data management process
- site monitoring process
- translation process

Study Organization



The Research Team is the principal decision making body regarding the scientific oversight of the study.

The Coordinating Center provides all aspects of study management and monitoring.

Study Advisors assist the Research Team and Coordinating Center with specific areas of expertise.

Site Investigators manage study sites within their country.

Study Advisors

- Depression (Psychiatry)

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- Economics

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- CIDI Trainers

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Site Investigators

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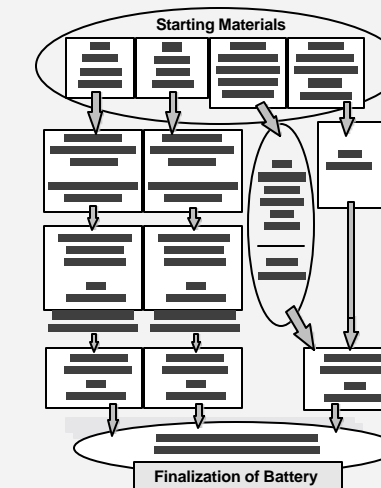
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Translation Process



Sample Checklist

Patient Management Checklist A
To be used between screening and determination of study status.

Patient Name: _____ Patient ID: _____

Date Screening Form Completed: ___/___/___ (From top of screening battery)

Date CES-D scored: ___/___/___ by: ___/___/___

CES-D Score: _____

Reported treatment for depression during past 3 months? YES NO

Plans to remain in area for next 12 months? YES NO

Determination of Study Status

Should patient be contacted for Baseline Visit? YES NO

Patient to complete Baseline Visit by: ___/___/___ (Within 2 weeks of screening date)

Assent by: ___/___/___

Date assigned: ___/___/___

Received on Positive Screen Log and Go to Checklist "C"

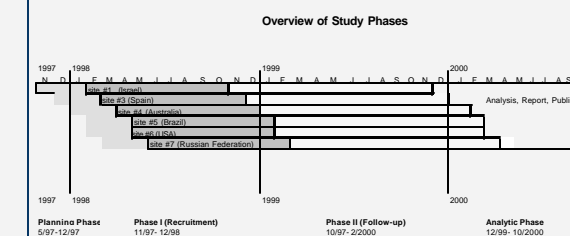
Complete Negative Screen Log

Randomized to Referral? YES NO

Complete negative screen log Go to Checklist "B"

1. Complete Negative Screen Log
2. Submit edited Screening Form to data entry.

Study Timeline



Conclusion

Multi-cultural studies always provide a richness and opportunity but difficulties for maintaining standardization. While it is possible to run international studies that yield poolable datasets, it requires intensive planning and set-up work in order to safeguard the quality of the data.