

STUDY SET-UP PROCEDURES

Country Feasibility Selection of National Sponsor

Site Feasibility

budget / location /
insurance / access to drugs
/ # of interested sites

experience / institutional
 support & resources /
 staff resources / budget

experience / commitment /
institutional resources /
staff resources / budget

Country Sponsor and Site Support

International Sponsor SickKids

Management of Database

International budget, payments

National Sponsor/
Coordinating Centre

Regulatory Ethics Support

Contracts

Site Activation

Set-up training

Regulatory Body Application, amendments, updates

Centralized
Application, or
supports local
applications

Set-up, training, safety reporting, ongoing support & communication