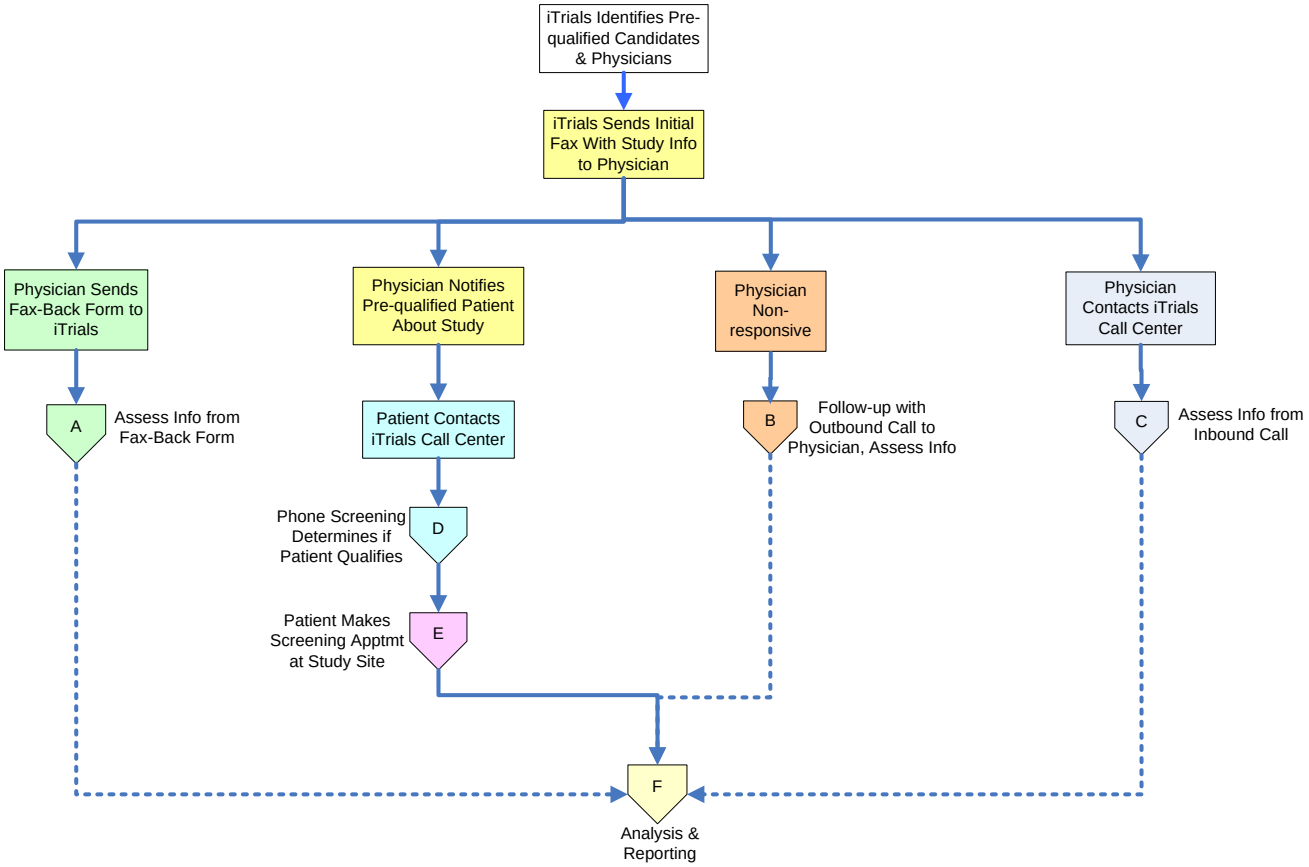
Cell Genesys: Vital 1 & Vital 2

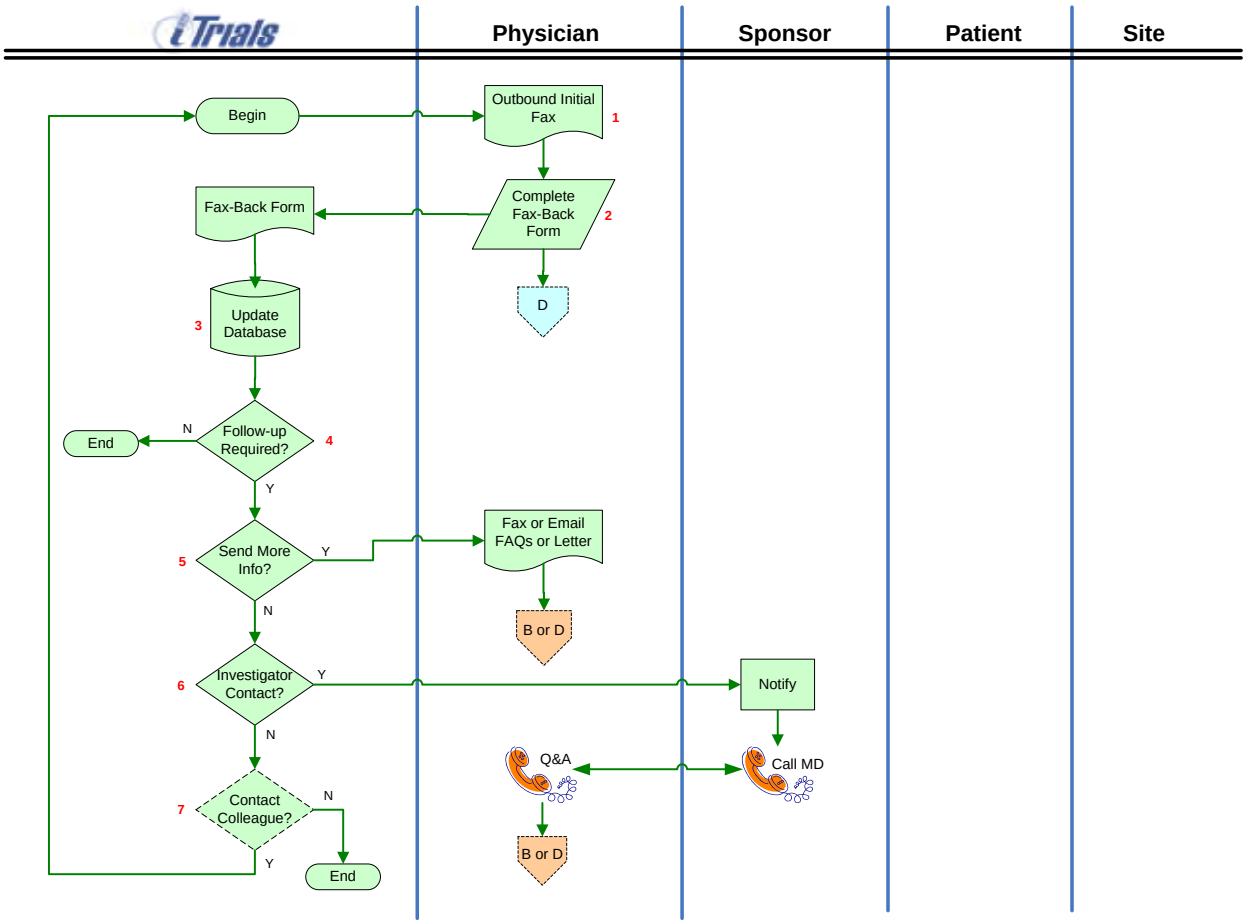
OUTREACH COMMUNICATIONS OVERVIEW



OUTREACH COMMUNICATIONS OVERVIEW

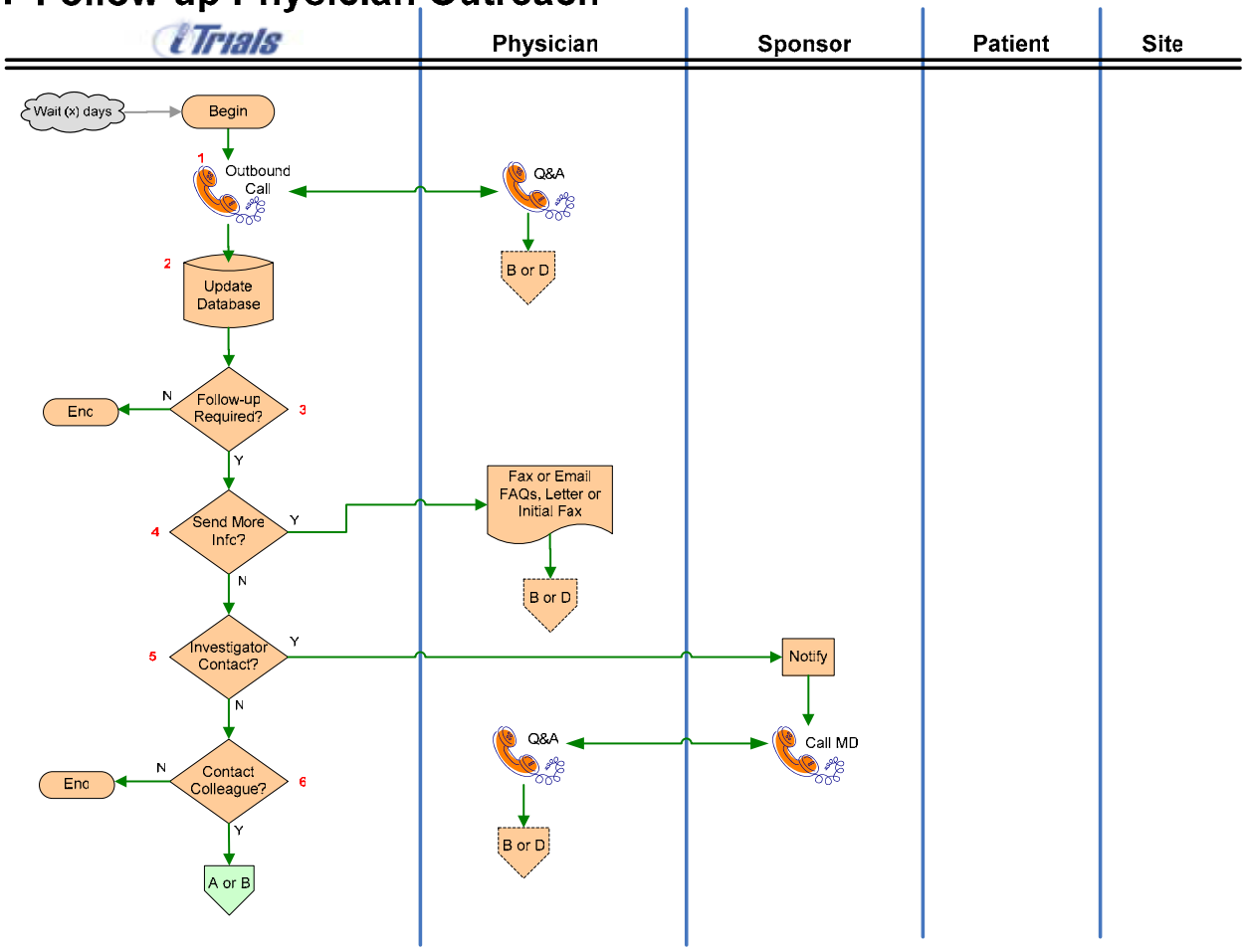
A. Initial Physician Outreach
B. Follow-up Physician Outreach
C. Inbound Physician Call
D. Inbound Patient Call
E. Patient Referral to Site
F. Recruitment Analysis

A. Initial Physician Outreach



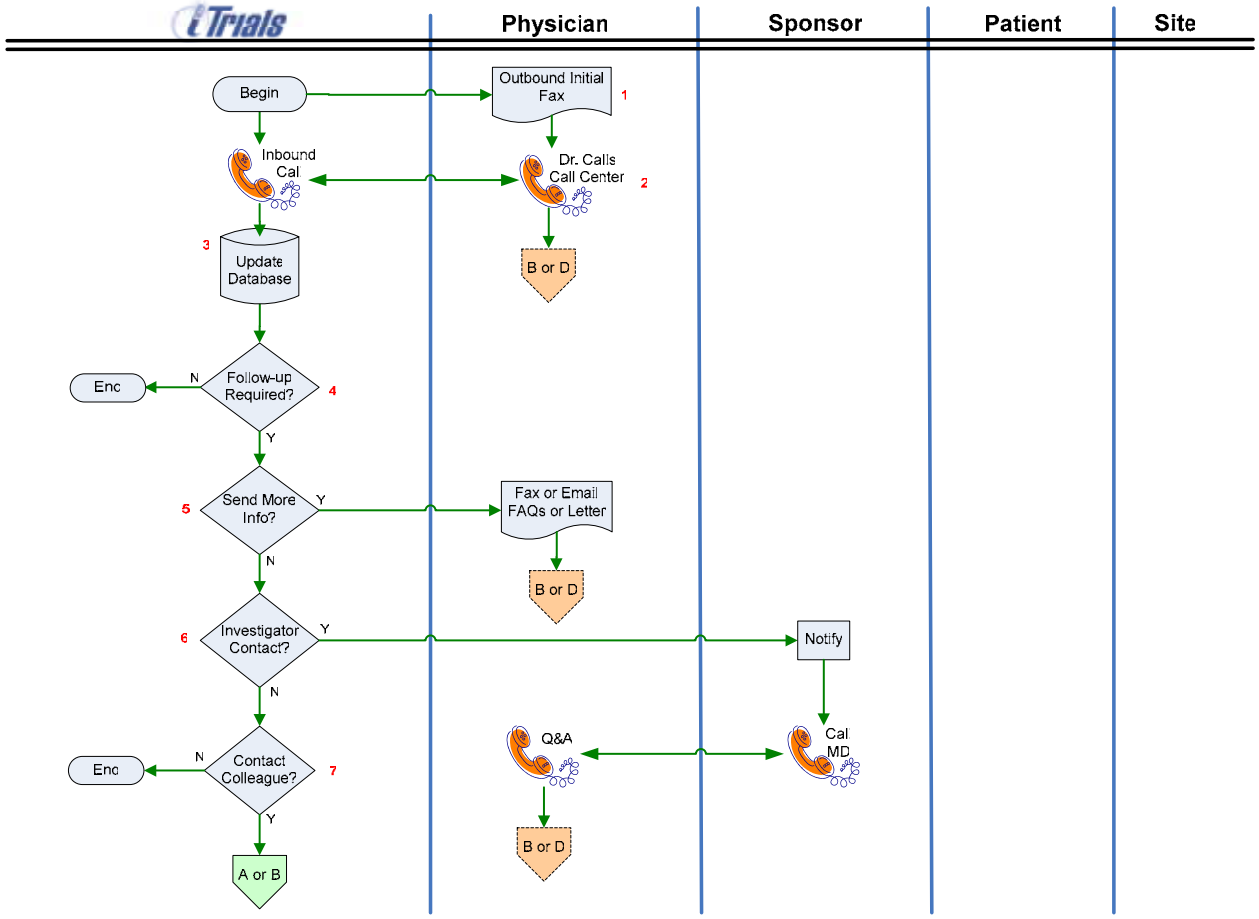
1. iTrials sends an outbound **Initial Fax** to physicians with pre-qualified patients, explaining the study opportunity, and requesting some brief information about eligible patients.
2. The physician completes the fax-back form with required information and sends to iTrials. (Note: expected compliance is 35-60%). After (x) days, if the fax-back form is not received, proceed to Process B. The physician may, after receiving the fax, contact his/her patient(s) and proceed to Process D.
3. iTrials assesses data from the fax-back form and updates the iTrials database.
4. The data is analyzed to determine the type of follow-up required. Physicians indicating they have no patients meeting the study criteria will not be contacted.
5. Physicians indicating needing additional information will be contacted. Depending on the physician's communication preference, information (the **Physician FAQs** and/or **Sample patient letter**) will be faxed or emailed to the physician. After (x) days, iTrials will proceed to Process B. The physician may, after receiving the additional information, contact his/her patient(s) and proceed to Process D.
6. iTrials will create a list of physicians (with contact info) who indicate on the fax-back form they wish to speak directly with the study's lead investigator. These requests will be sent to Dr. Chondros, so that he may contact the physicians directly. This physician-to-physician communication is designed to answer any questions the physician has about specific medical issues affecting trial participation. After (x) days, iTrials will proceed to Process B. The physician may, after talking with the study investigator, contact his/her patient(s) and proceed to Process D.
7. *Optional:* If the physician indicated on the fax-back form that a colleague may be interested in this study, iTrials will utilize this contact info from the physician to begin a new outbound fax (see **Physician Colleague Fax**) to that physician. This new outbound fax will be slightly different from the original fax in that it will not refer to specific pre-qualified patients. However, it will have a similar fax-back form, and Process A begins anew. If the colleague is already in the iTrials database, and that physician has not yet responded previously, iTrials will follow-up with Process B.

B. Follow-up Physician Outreach



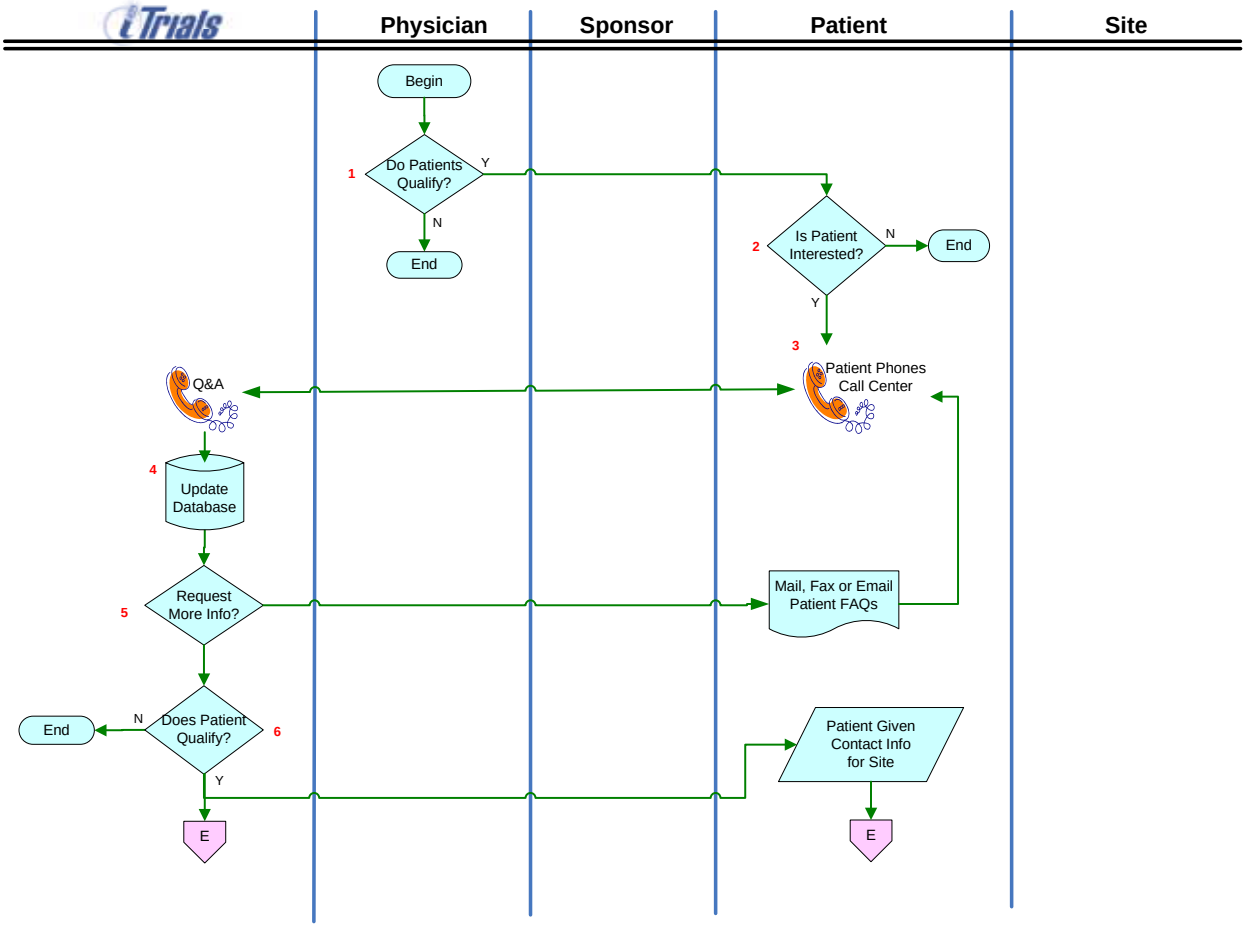
1. If no fax-back form is received after (x) days after the **Initial Fax** was sent to the physician, the iTrials call center will initiate an outbound call to the physician. Through strategic questions and answers (see **Physician Outbound Call Script**), information will be gathered and assessed by the iTrials call center.
2. Data from the call will be utilized to update the iTrials database and to determine the type of follow-up required.
3. Physicians who verbally indicated that they have no patients that meet the study criteria, will not have any further follow-up. Physicians who indicated they want additional information will be contacted.
4. Depending on the physician's communication preference, the information requested (**Physician FAQs**, **Sample patient letter**, and/or **Initial Fax** again) will be faxed or emailed to the physician. After (x) days, Process B may be initiated again. The physician may, after receiving the additional information, contact his/her patient(s) and proceed to Process D.
5. iTrials will create a list of physicians (with contact info) who verbally indicate wanting to speak directly with the study's lead investigator. These requests will be sent to Dr. Chondros, so that he may contact the physicians directly. This physician-to-physician communication is designed to answer any questions the physician has about specific medical issues affecting trial participation. After (x) days, Process B may be initiated again. The physician may, after talking with the study investigator, contact his/her patient(s) and proceed to Process D.
6. If the physician indicates a colleague may be interested in this study, iTrials will utilize this contact info from the physician to begin a new outbound fax (see **Physician Colleague Fax**) to that physician. This new outbound fax will be slightly different from the original fax in that it will not refer to specific pre-qualified patients. However, it will have a similar fax-back form, and Process A begins anew. If the colleague is already in the iTrials database, and that physician has not yet responded previously, iTrials will follow-up with Process B.

C. Inbound Physician Call



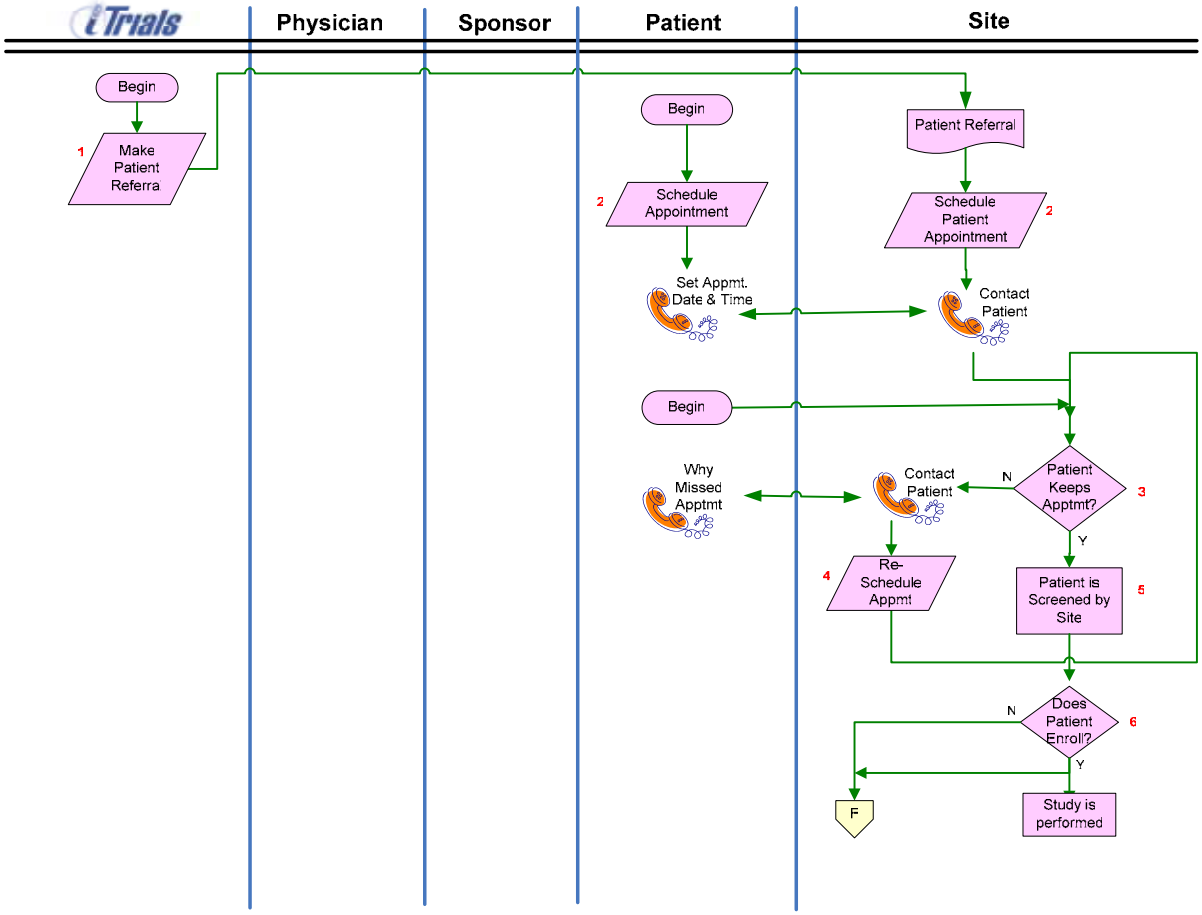
1. iTrials sends an outbound **Initial Fax** to physicians with pre-qualified patients, explaining the study opportunity, and requesting some brief information about eligible patients.
2. The physician calls the toll-free number (the iTrials call center) directly. Through strategic questions and answers (see **Physician Inbound Call Script**), information will be assessed by the call center.
3. iTrials assesses data from the physician call, updates the iTrials database, and determines the type of follow-up required.
4. Physicians indicating they have no patients meeting the study criteria will not be contacted. Physicians requesting additional information will be contacted.
5. Depending on the physician's communication preference, the information requested (the **Physician FAQs** and/or **Sample patient letter**) will be faxed or emailed to the physician. After (x) days, Process B may be initiated. The physician may, after receiving the additional information, contact his/her patient(s) and proceed to Process D.
6. iTrials will create a list of physicians (with contact info) who indicate wanting to speak directly with the study's lead investigator. These requests will be sent to Dr. Chondros, so that he may contact the physicians directly. This physician-to-physician communication is designed to answer any questions the physician has about specific medical issues affecting trial participation. After (x) days, Process B may be initiated again. The physician may, after talking with the study investigator, contact his/her patient(s) and proceed to Process D.
7. If the physician indicates a colleague may be interested in this study, iTrials will utilize this contact info from the physician to begin a new outbound fax (see **Physician Colleague Fax**) to that physician. This new outbound fax will be slightly different from the original fax in that it will not refer to specific pre-qualified patients. However, it will have a similar fax-back form, and Process A begins anew. If the colleague is already in the iTrials database, and that physician has not yet responded previously, iTrials will follow-up with Process B.

D. Inbound Patient Call



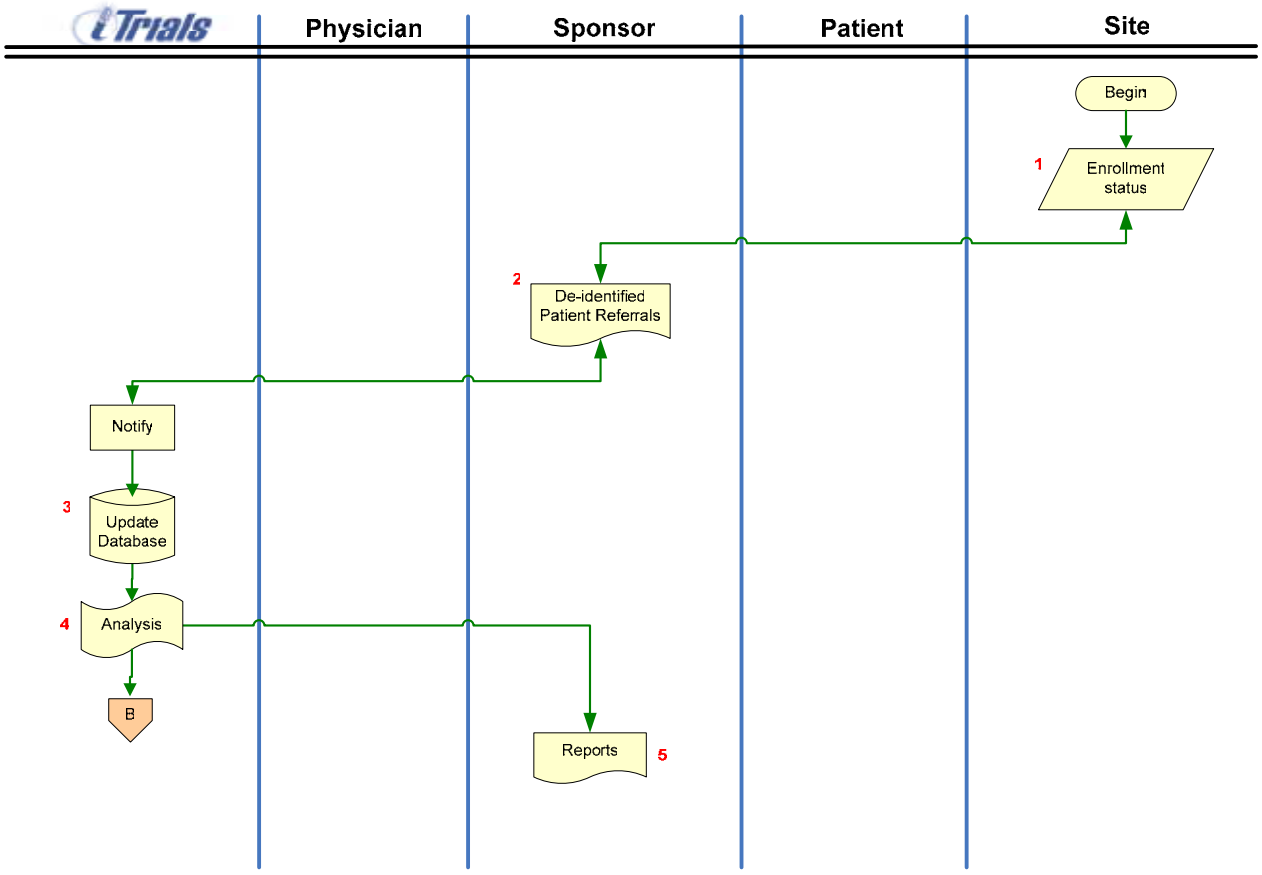
1. Physicians familiar with this trial (via Processes A, B, or C) will determine whether any of their patients should inquire about this trial. If the physician believes his/her patient qualifies for this trial, the physician will contact the patient using a method of his/her choice (e.g., letter, call, appointment).
2. If the patient is interested in the trial, they will be instructed by their physician to call the iTrials toll-free number (iTrials call center).
3. Through strategic questions and answers (see **Patient Recruitment Script**), information will be gathered and assessed by the call center.
4. Data from the call will be utilized to update the iTrials database and to determine the type of follow-up required.
5. If the patient requests more information before consenting to be screened for the trial, the **Patient FAQs** may be sent to the patient via their preferred method (fax, email, mail). After reviewing this information, the patient will call the iTrials call center again and request to be screened for this trial. (Note: after (x) days, if there is no response from the patient, the iTrials call center will initiate a call to the patient.)
6. The iTrials call center professionals will determine, based on the Q&A, whether the patient qualifies for Vital-1 or Vital-2. If the patient qualifies for Vital-1, the call center will refer the patient to the closest Vital-1 site, giving the patient the contact information for that site. If the patient qualifies for Vital-2, the call center will refer the patient to the closest Vital-2 site, giving the patient the contact information for that site. Both iTrials and the patient proceed with Process E.

E. Patient Referral to Site



1. iTrials notifies each site (via email or fax) about the patients it has referred to their site for screening. Complete patient information is provided (contact info, physician, patient's responses to Patient Call Center Script, iTrials ID#) for each candidate.
2. The site contacts the patient, or the patient contacts the site, and schedules an appointment for the patient to come in and be screened. (x) days after the referral is received by the site, if the patient has not yet contacted the site, the site will contact the patient.
3. The patient will present to the site at the appointed date and time. If a patient does not present for their screening appointment, the site will contact the patient and inquire why the appointment was missed.
4. If the patient is still interested and eligible, the site will reschedule the patient for another appointment.
5. At the screening appointment, the study is explained in detail to the patient and the investigator determines whether the patient meets all study criteria.
6. If the patient does not meet study criteria or does not give consent, then the patient is not enrolled. If the patient meets all study criteria and gives consent, the patient is enrolled and participates in the study. Continue with Process F.

F. Recruitment Analysis



1. On a continuous basis (interval TBD) each site provides the sponsor an updated status of patient enrollment at their site, using the iTrials ID#, i.e., de-identified patient data.
2. The sponsor, on a continuous basis (interval TBD), provides iTrials notification of patient enrollment status, using the iTrials ID# (de-identified patient data).
3. iTrials updates their recruitment database with enrollment data provided by sponsor.
4. iTrials analyzes response data to determine whether pre-qualified patients expected to respond have done so. If fewer patients per physician have contacted the iTrials call center than expected, Process B is initiated again with the targeted physicians.
5. iTrials furnishes Cell Genesys reports on recruitment progress, opportunities for process improvements, and statistical analysis.

