PATIENT RECRUITMENT PLAYBOOK

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SubjectWell

parexel®

Overview

ROLES AND RESPONSIBILITIES FOR:

Introduction and Purpose of Playbook

The Patient Recruitment Playbook is a collaboration between PXL and SubjectWell. It is designed to leverage SubjectWell's operational standards and working relationship with PXL to provide guidance and support for the entire lifecycle of the patient recruitment journey.

Timeline Management: Detailed guidance will be provided to the SubjectWell and PXL project/study teams so they can more readily anticipate each milestone through the recruitment lifecycle.

Escalations: Provide clear definitions on escalations and a clear pathway to manage escalations quickly and effectively.

Continuous Improvement: Establish a continuous improvement culture to leverage lessons learned/process review meetings at specific recruitment milestones.

Efficiency: We aim to use all previous experiences to establish and maintain efficiencies in future studies.

Cultural and DEI Alignment: Utilize the historic knowledge of PXL and SubjectWell's working cultures to clarify terminology, roles and responsibilities, hierarchy and expectations, while maintaining the highest diversification standards.

PROCESS FOR PRE-AWARD / PROPOSAL / QUOTE STAGE

- SubjectWell requests the following for RFP: Protocol / Synopsis, Site locations with specificity of geographic city (N/A for Pre-Award stage) / region, patient recruitment timelines, FPI, and LPI from PXL, completed SubjectWell proposal form (Found on PXL landing page, internally, or requested from jeremy.westfall@subjectwell.com)

- Any questions will be addressed back to PXL PRL

- SubjectWell will provide ballpark / proposal and simulation of study.

- Include: which areas of the patient recruitment are at risk:
  - Timelines based on randomization numbers.
  - Randomization numbers as a whole.
  - Pricing risk factors for PXL to win. Open communication between SubjectWell and PXL to best strategize to win.
  - Site appointment scheduling vs. SubjectWell site appointment scheduling.

- Understand financial risks if the study is terminated early.

PROCESS FOR PRE-AWARD / PROPOSAL / QUOTE STAGE

Pre-Award Focus

- PXL procurement SME for high spend, complex, patient recruitment opportunities / projects.

- SubjectWell and PXL analyze protocol and quote for best "match" measuring and mitigating cost avoidance and facilitating reduction in change orders.

- Provide access to Patient Recruitment Playbook to PXL proposals manager/ study team.

Pre-Award and Quote Requirements

- Parexel Proposals Manager to provide:
  - Protocol or Protocol Synopsis with site specific locations (City, State, Country), patient referral numbers, patient randomization numbers, FPI, LPI, medical record need, virtual waiting room need, etc.
  - Open communication on pricing needs to be included in the above. PXL to also have high communication with SubjectWell for pricing modalities.

SubjectWell to provide:

- Partner discount pricing quote, simulation, detailed proposal on market strategy for patient recruitment

PROCESS FOR PRE-AWARD / PROPOSAL / QUOTE STAGE

When a new project has been awarded, SubjectWell PM & PXL PRL to ensure **final** proposal is included in client budget.

Levels of detail in final proposal to include: level of experience of SubjectWell, pricing with simulation, and patient recruitment strategy.

The SubjectWell Relationship Manager and PXL Patient Recruitment Team will be responsible for providing the Patient Recruitment Playbook to the appropriate study team members.

The Patient Recruitment Playbook will be rolled out at both SubjectWell and Parexel, to ensure the steps are clearly understood by SubjectWell PMs and PXL PRL's, who will leverage this document throughout the patient recruitment lifecycle.

Upon pre-award review, playbook will also be shared with PXL Study Team.

Timelines: 48-72 hours KOM post P.O. Recruitment starts immediately following site training and any collateral that needs to be produced.

Initial Project KOM Agenda Topics

- SubjectWell's Non-Traditional Approach To Patient Recruitment

- SubjectWell Overview

- Patient Journey

- Our Site Support Leadership Team Introductions

- Connecting with Referrals

- SMS Capabilities

- Escalation Feedback Plan

- Patient Nurturing

- Launching Your Site and How to Make it Successful

ROLES AND RESPONSIBILITIES: KICK-OFF MEETING (KOM)

SubjectWell PM

- To be assigned to project and Jeremy Westfall will make introduction from the SubjectWell PM to the PXL team..

- SubjectWell PM will set up an introductory call with PXL patient recruitment lead to introduce themselves, verify project scope and plan the next steps (KOM).

- SubjectWell PM will provide escalation contacts to PXL's patient recruitment teams, as well as provide any appropriate training needed for PXL, or sponsor.

- SubjectWell PM will provide all patient support documentation and all SubjectWell contact information should the patient need it.

- SubjectWell will provide all communication needed to the sites where SubjectWell will be scheduling appointments.

- SubjectWell will provide an SME to cover any Bid Defense or participate in any call where a sponsor may need further information on who / how Subjectwell works.

PXL PL/ Sponsor

- Signed Work Order / P.O. is needed prior to activities start. Prepare details such as: Site information, inclusion/exclusion criteria, suggested changes for modified screening questions (Complex study, RWE study, or Hybrid), and IRB submission requirements and dates. No WAR at Risk.

- Through PXL, Sponsor to provide any protocol modifications 2 weeks in advance of kick-off meeting for SubjectWell agreement. If protocol is not final, planned date of finalization and what, if any, will be the impact on patient recruitment quote and/ or timelines.

All Parties

- Ensure comprehensive communication and appropriate information is shared as much as possible.
- Regular meeting cadence and attendees to be agreed between PXL and SubjectWell.
- PXL-SubjectWell SOW / P.O. executed upon study award and client contract execution.

ROLES AND RESPONSIBILITIES: STUDY MAINTENANCE (POST-GO LIVE)

SubjectWell	- Hold status meetings based on PXL expectation. Capture everything, in CRO and Sponsor dashboards. - Facilitate / modify algorithms based on recruitment and if change orders are needed to modify contract based on resourced capabilities, PXL to be notified and a scheduled call for explanation will be executed. - Notify study team of any upcoming maintenances. Unscheduled maintenances shared ASAP (within a day).
Sponsor	All dependent on Sponsor and Parexel agreement, but the below listed items are acceptable. - Attend status meetings and acknowledge documentation in CRO and Sponsor dashboards. - Crucial to communicate Protocol Amendments / screening criteria and changes in contracting must be communicated in advance. - Support that changes the scope will require modifications to the contract with PXL but should not hinder ongoing recruitment, thus facilitate easy Change Order execution between PXL and SubjectWell. **PXL and SubjectWell should not be working without a signed change order, ~~unless both parties agree in written format (Email, etc.).~~**
PXL	- Attend status meetings and acknowledge documentation in CRO and Sponsor dashboards. - Monitor site referrals and randomizations for trends and review with SubjectWell. - Monitor data to ensure accuracy and compliance for any recruitment modification discussions that may need to take place. - e.g.: sites are communicating with PXL on referral follow through, subject numbers are correct, randomizations are entered in timely fashion. - Complete monthly data tracking with SubjectWell for recruitment effectiveness / any modification needed. - Work with sponsor and SubjectWell on any project scope changes: **Sponsor CIS with adequate financial coverage must be executed prior to the SubjectWell Change Order. SubjectWell must have signed contract (CO) in place when scope of work increases.**

ROLES AND RESPONSIBILITIES
STUDY CLOSE-OUT: TO COMMENCE 3 MONTHS PRIOR TO LPLV

SubjectWell

- Review with PXL PRL milestones, contingencies, timelines.

- Facilitate documentation for both parties acknowledging that the study is coming to a close, regardless of reason..

- Prepare Customer Care that study is closing.

- Address any open issues assigned to SubjectWell.

- Lock database, facilitate final recon with PXL, and send final data transfer

- Send any and all data requested, including the final report.

- Facilitate budget reconciliation and final invoice by SubjectWell
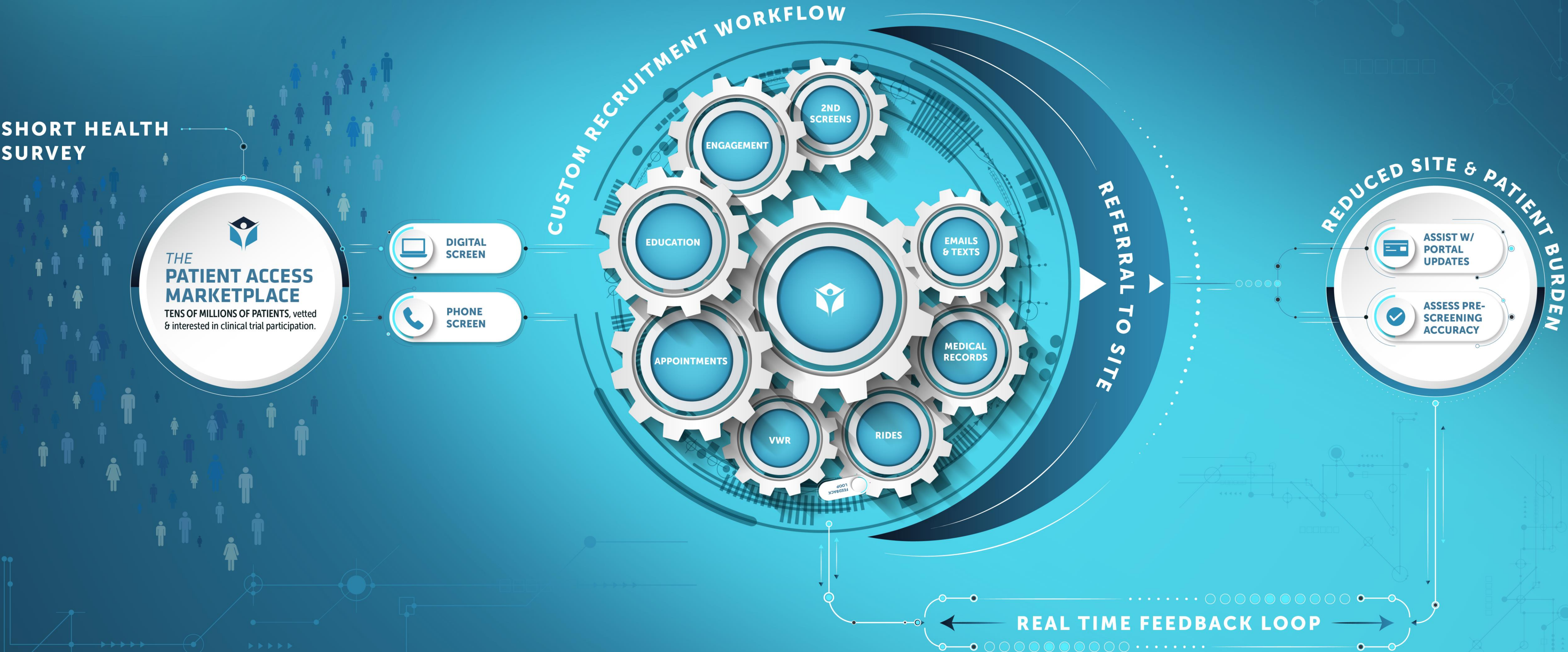
PXL PRL

- Review and accept final results.

- Sign-off on SubjectWell close-out documentation.

- Work with SubjectWell on final invoice and with PXL Procurement on updating final version of PO.

All Parties

- Conduct lessons learned meeting & review with teams and appropriate stakeholders.

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SubjectWell