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# **Introduction**

The IMPACT Roadmap is the result of Project IMPACT, a two-year, PCORI-funded engagement project (Contract #30455) led by PFIC Network. Developed through extensive collaboration with patients, caregivers, clinicians, and researchers, it outlines strategies and priorities for PFIC-specific CER that align with patient needs and clinical perspectives. This Researcher Companion complements the roadmap by offering practical tools and guidance for implementing its recommendations and conducting meaningful, patient-centered comparative clinical effectiveness research in PFIC.

**Patient-centered Comparative Clinical Effectiveness Research (PC-CER)** is research that (1) compares the effectiveness of two or more established treatments, services or practices, and that (2) focuses on outcomes that are directly relevant to patients and their caregivers.1

A key feature of patient-centered CER is patient and stakeholder **engagement**. As defined by the Patient-Centered Outcomes Research Institute (PCORI), engagement in research means the “meaningful involvement of patients, caregivers and others in the broader healthcare community throughout the research process - from topic selection through design and conduct of research to dissemination of results.” 2

In Project IMPACT, PFIC patients, parents, clinicians, and researchers jointly identified the most pressing treatment questions and relevant outcomes for future CER as well as the conditions and strategies needed to build strong multi-stakeholder teams and design meaningful, patient-centered studies. This companion provides an overview of the work accomplished during IMPACT and can serve as a practical manual for planning a patient-centered CER study in PFIC. It includes worksheets, checklists, and planning tools to help:

* build and sustain engagement with PFIC patients, parents, and other stakeholders at every stage - from planning a study to the dissemination of study results.
* design a PFIC CER study around patient-defined priorities.

The companion is designed for researchers at the early stages of planning and aims to support thoughtful, community-informed study development. We hope you find it useful - and we appreciate your interest in including the voices of those living with PFIC in your research!

**References:**

1 <https://www.pcori.org/research-related-projects/about-our-research/research-we-fund>

2 <https://www.pcori.org/funding-opportunities/what-you-need-know-apply/glossary>

# **Step 1 – Initial Study Planning**



**Overview**

IMPACT participants emphasized the importance of designing patient-centered CER studies in PFIC that tackle questions most important to patients¹, prioritize real-world outcomes², and integrate patient input throughout all stages of research3. While these elements are central to patient-centered CER generally, they were highlighted by the PFIC community in IMPACT as especially critical. This section provides tools and templates to support study design that incorporates these priorities.

Contents

1. **Study Orientation (PICOT)** – A worksheet for outlining the study objective and research question using the PICOT framework.
2. **Guiding Principles** – A checklist to align the study objective, research question, and engagement plan with patient priorities.

**References:**

1 <https://www.pcori.org/research-related-projects/about-our-research/research-we-fund>

2 <https://www.pcori.org/sites/default/files/PCORI-Principles-for-Consideration-of-Full-Range-of-Outcomes-Data-in-PCORI-Funded-Research.pdf>

3 <https://www.pcori.org/engagement-research/engagement-resources/foundational-expectations>

## Study Orientation (PICOT) Worksheet

**Instructions:** Starting with a clear objective and research question helps guide subsequent study design. This worksheet applies the PICOT framework¹ - Population, Intervention, Comparator, Outcomes, and Timeframe - to provide structure for formulating the research question. The elements captured here serve as a reference point throughout the companion and may be revisited and refined as planning evolves.

1Riva JJ, Malik KM, Burnie SJ, Endicott AR, Busse JW. *What is your research question? An introduction to the PICOT format for clinicians*. J Can Chiropr Assoc. 2012 Sep;56(3):167-71. PMID: 22997465; PMCID: PMC3430448.

|  |  |
| --- | --- |
| **Planning Prompt** | **Notes** |
| **Study Objective(s)** | *Example(s): to compare the effectiveness of IBAT inhibitors alone versus in combination with rifampin in reducing itch and improving quality of life for children with PFIC* |
| **Population** | *Example(s): children and adolescents (ages 2-18) diagnosed with FIC1 and BSEP* |
| **Interventions/Comparators** | *Example(s): IBAT inhibitor, IBAT inhibitor + rifampin* |
| **Outcomes** | *Example(s):* * *primary: reduction in itch severity (patient-reported outcome), improvement in sleep quality*
* *secondary: growth parameters, liver function biomarkers, transplant-free survival, caregiver stress, school/work attendance, financial burden*
 |
| **Time Frame** | *Example(s): 12 months of treatment with follow-up at 3, 6, and 12 months; longer-term outcomes assessed at 24 months* |

## Guiding Principles for Study Planning Checklist

**Instructions:** This checklist supports alignment of study plans with core aspects of patient-centered CER and the three guiding principles identified in IMPACT: being **outcomes-driven** by focusing on patient priorities and real-world impact, **patient-centric** by integrating ongoing patient input into study methods, and **transparent** by providing clear communication at every stage.

🖱️: ̗̀➛ *IMPACT Roadmap Section:* [*https://impactroadmap.pfic.org/guiding-principles-for-pfic-patient-centered-cer-projects/*](https://impactroadmap.pfic.org/guiding-principles-for-pfic-patient-centered-cer-projects/)

|  |  |  |
| --- | --- | --- |
| **Principle** | **Planned?** | **Approach** |
| **Outcomes-Driven**  |
| Findings from Project IMPACT - such as patient-identified treatment questions or outcomes - were used to shape the study | ☐ | *Example(s): see “Community-Identified Questions” and “Community-Identified Outcomes” sections on the IMPACT roadmap page* [*PFIC Patient-Centered CER Priorities*](https://impactroadmap.pfic.org/pfic-patient-centered-cer-priorities/) |
| Study addresses a real-world decisional dilemma reported by PFIC patients and caregivers  | ☐ | *Example(s): families must decide whether to use an IBAT inhibitor alone or combine it with other medications to manage PFIC symptoms. While combination therapy might offer greater itch relief or improved quality of life, it could also mean a higher pill burden, more side effects, and greater cost* |
| Research has the potential to improve quality of life, not just clinical outcomes | ☐ | *Example(s):* *by comparing interventions’ impact on itch relief, sleep, and family quality of life, this study aims to address the daily burdens of PFIC - not just lab values or transplant-free survival* |
| Study considers social, emotional, or financial impacts of the disease or its treatments | ☐ | *Example(s): study incorporates measures of caregiver stress, out-of-pocket treatment costs, and the effect of intervention on school and work attendance* |
| **Patient-Centric** |
| Study population is representative | ☐ | *Example(s): study population represents different subtypes, age groups, transplant status, and geographies* |
| Patients and/or parents are part of the core research team or engaged as meaningful contributors  | ☐ | *Example(s): parents of children with PFIC serve as co-investigators, participating in study design, recruitment strategy, and dissemination planning* |
| There are plans for ongoing patient involvement and shared decision-making throughout the project | ☐ | *Example(s): multi-stakeholder steering committee (patients, caregivers, clinicians, researchers, statistician) will meet quarterly to review progress, troubleshoot challenges, and approve major study decisions* |
| Patients have flexible, accessible opportunities to provide input  | ☐ | *Example(s):* *opportunities include online surveys for reviewing study materials, virtual focus groups scheduled across time zones, and one-on-one interviews for those unable to attend group sessions* |
| **Transparent** |
| There are plans to share study progress and results with PFIC families in real time and after completion  | ☐ | *Example(s): quarterly plain-language progress updates via PFIC Network email newsletter; summaries posted on PFIC.org and shared in live virtual town halls* |
| Key study materials written in clear, plain language | ☐ | *Example(s):* *consent forms rewritten for an 8th-grade reading level; study summaries designed with visuals and infographics to aid understanding* |
| Participants will know how their feedback is being used and see the impact of their involvement | ☐ | *Example(s):* *after each engagement activity, participants receive a short “You Said / We Did” update showing how their input influenced protocol changes, outcome measures, or recruitment approaches* |

# **Step 2 – Clarifying Engagement Structure**



**Overview**

A foundational tenet of patient-centered CER is the meaningful and active involvement of patients as equal partners at every stage of research, from study design to the dissemination of findings1. This approach ensures that research methods and goals integrate patient priorities and needs, and that the resulting evidence is directly relevant for patients’ lives.

This section offers tools and templates to help structure, manage, and sustain meaningful partnerships with patients throughout a PFIC patient-centered CER project.

Contents

1. **Infrastructure** – A worksheet for outlining the engagement structure (e.g., core research team, advisory groups) and stakeholder roles.
2. **Management** – A planning tool for managing multi-stakeholder research teams and ensuring meaningful patient involvement.
3. **Barriers & Solutions** – A checklist for proactively addressing patient-identified barriers to engaging in research teams.

**References:**

1 <https://www.pcori.org/sites/default/files/PCORI-Foundational-Expectations-for-Partnerships-In-Research.pdf>

### Infrastructure Worksheet

**Instructions:** Designing a PFIC patient-centered CER study requires structuring stakeholder involvement across the full research cycle. This worksheet can help build a practical, intentional engagement infrastructure that ensures diverse patient and stakeholder voices are included and sustained throughout a project. In each section, prompts can be used to sketch out who will be involved, what roles stakeholders will play (e.g., core team, advisory, rotating contributor), and when and why their input will be sought.

🖱️: ̗̀➛ *IMPACT Roadmap Section:* [*https://impactroadmap.pfic.org/guidance-for-forming-successful-multi-stakeholder-pfic-research-teams/*](https://impactroadmap.pfic.org/guidance-for-forming-successful-multi-stakeholder-pfic-research-teams/)

1. **Core Research Team**

Ongoing members involved throughout the full study lifecycle.

|  |  |
| --- | --- |
| **Planning Prompt** | **Notes** |
| **How many members?** | *Example(s): 4-6 members based on availability and interest*  |
| **Which roles will be included?** | *Example(s): (recommended) patients, parents, clinicians, researchers, statistician* |
| **How often will the core team meet?** | *Example(s): weekly, monthly, bi-monthly, quarterly* |
| **How will decisions be made?** | *Example(s): consensus, majority vote, PI-led with input*  |
| **How will core team members be compensated?** | *Example(s): see* [*NHC Patient Engagement Fair-Market Value Calculator*](https://nationalhealthcouncil.org/access-the-fmv-calculator/) |

1. **Advisory Groups**

Stakeholder groups who provide input at key moments.

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| **Planning Prompt** | **Notes** |
| **Will you have a single advisory group or multiple?**  | *Example(s): one patient/parent advisory council, one adolescent advisory board* |
| **Who will participate and how many members?**  | *Example(s): PFIC parents and caregivers, patients over the age of 14 years old* |
| **At what stages will they contribute?** | *Example(s): study design, recruitment, dissemination* |
| **How will you gather their input?** | *Example(s): live meetings, surveys, asynchronous review via email* |
| **How will their input be integrated and shared back?** | *Example(s): recurring email updates, virtual meetings* |
| **How will advisory group members be compensated?**  | *Example(s): see* [*NHC Patient Engagement Fair-Market Value Calculator*](https://nationalhealthcouncil.org/access-the-fmv-calculator/) |

1. **Rotating Contributors**

Subject matter experts or stakeholder members engaged for a defined period or purpose.

|  |  |
| --- | --- |
| **Planning Prompt** | **Notes** |
| **Which roles might rotate in and out?** | *Example(s): (recommended) psychologist, child life specialist, research assistant, communication specialist* |
| **What triggers their involvement?** | *Example(s): pediatric study population, results dissemination* |
| **At what stages will they contribute?** | *Example(s): study design, data analysis, creation of dissemination material*  |
| **How will you onboard them quickly and clearly?**  | *Example(s): orientation call, virtual training modules, digital resource hub* |
| **How will they coordinate with the core team and/or advisory group(s)?** | *Example(s): email communications, virtual meetings* |
| **How will rotating contributors be compensated?** | *Example(s): stipends, hourly payment, authorship or acknowledgement* |

1. **Pediatric Patients (if applicable)**

Structures to include children and teens in age-appropriate ways.

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| --- | --- |
| **Planning Prompt** | **Notes** |
| **What age group(s) will you include?** | *Example(s): pediatric patients ages 8–13 years old, patients over the age of 14*  |
| **What triggers their involvement?** | *Example(s): study protocol design* |
| **What engagement strategies will you use?** | *Example(s):* *focus groups with visual tools, teen advisory board* |
| **Who will facilitate their participation?** | *Example(s):* *core research team member, child life specialist, psychologist* |
| **How will their input be integrated and shared back?** | *Example(s): short video explainers, social media or email updates*  |
| **How will pediatric patient partners be compensated?** | *Example(s): see* [*NHC Patient Engagement Fair-Market Value Calculator*](https://nationalhealthcouncil.org/access-the-fmv-calculator/) |

### Management Planning Tool

**Instructions:** This planning tool establishes the resources and practices necessary to support patients and other stakeholders as equal partners. Checking and outlining an approach for each strategy helps ensure meaningful participation across all phases of the project.

|  |  |  |
| --- | --- | --- |
| **Strategy** | **Planned?** | **Approach** |
| **Section 1:**  |
| Clearly define partner roles & responsibilities  | ☐ | *Example(s): produce a Scope of Work (SOW) or Memorandum of Understanding (MOU) for each individual partner* |
| Offer partners fair financial compensation for time and effort | ☐ | *Example(s): see* [*NHC Patient Engagement Fair-Market Value Calculator*](https://nationalhealthcouncil.org/access-the-fmv-calculator/)*, consider additional support to eliminate participation barriers such as reimbursement for childcare services* |
| **Section 2: Project Management** |
| Create a project timeline with clearly defined milestones | ☐ | *Example(s): generate using spreadsheet or chart graphic*  |
| Break partner tasks into manageable parts | ☐ | *Example(s): divide tasks into smaller steps using a shared checklist with clear deadlines*  |
| **Section 3: Communication**  |
| Identify preferred communication tools & platforms | ☐ | *Example(s): poll patient and stakeholder partners during kickoff meeting for preferred tools (e.g., email, shared folders, project management software)*  |
| Assess partner time zones  | ☐ | *Example(s): poll patient and stakeholder partners for their time zones and schedule meetings to accommodate all in one* ***or*** *organize multiple meetings to accommodate separately* |
| Define methods for sharing updates and decisions  | ☐ | *Example(s): brief weekly email summaries, shared decision log in Google Docs, reserved time during standing meetings* |
| **Section 4: Onboarding & Training** |
| Train partners on research processes and terms  | ☐ | *Example(s): provide plain-language written guides, share brief (<10 min) explainer videos* |
| Provide ongoing partner support  | ☐ | *Example(s): offer 1:1 mentorship and monthly check-ins (call or email); create onboarding strategy for new/temporary contributors* |
| Host an in-person meeting(s) to foster collaboration & trust | ☐ | *Example(s): organize a workshop at start of each project year incorporating team-building activities* |
| **Section 5: Evaluation** |
| Continuously evaluate participation & engagement | ☐ | *Examples: distribute* [*PEET survey*](https://pubmed.ncbi.nlm.nih.gov/34852275/) *to patient and stakeholder partners following each meeting* |

Barriers & Planned Solutions Checklist

**Instructions:** This checklist highlights common barriers to patient partnership teams highlighted in IMPACT and provides space to document solutions. Anticipated barriers can be marked and addressed in the adjacent column.

🖱️: ̗̀➛ *IMPACT Roadmap Section:* [*https://impactroadmap.pfic.org/barriers-solutions-to-patient-researcher-partnerships/*](https://impactroadmap.pfic.org/barriers-solutions-to-patient-researcher-partnerships/)

|  |  |  |
| --- | --- | --- |
| **Barriers** | **Planned?** | **Approach** |
| **Time Constraints**Partners navigate busy schedules between work, school, and hospital visits. | ☐ | *How will your engagement plan reduce time burden and/or increase flexibility?**→ e.g., sending materials in advance, shortening activities* |
| **Logistical Challenges**Partners encounter challenges related to transportation, childcare, or access to technology. | ☐ | *How will you support partners logistically?**→ e.g., offering virtual participation, providing childcare stipends or travel support,* |
| **Limited Research Experience**Partners unfamiliar with CER, scientific terms, or the research process. | ☐ | *How will you make participation approachable?**→ e.g., providing plain-language education materials, short video explainers, live Q&A* |
| **Low Confidence** Partners unsure how their input will be used or valued. | ☐ | *How will you ensure partner contributions feel meaningful?**→ e.g., co-develop study aims, explain how feedback shapes decisions, shared decision-making protocols* |
| **Cultural/systemic barriers**Partners experience mistrust of healthcare institutions, face language barriers, or encounter systemic obstacles such as socioeconomic inequities. | ☐ | *How will you build trust and ensure equity of engagement?**→ e.g., use inclusive outreach, collaborate with trusted community leaders, translate materials* |

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# **Step 3 – Finalizing & Preparing for Implementation**



**Overview**

Another essential aspect of patient-centered CER is ensuring studies minimize burden on participants1, and that results are communicated back to participants and the broader stakeholder community in meaningful ways2. Participants in Project IMPACT recommended strategies to reduce barriers to participation and to strengthen approaches for sharing study findings. This section provides worksheets and planning tools to help integrate these strategies into PFIC patient-centered CER, supporting studies that are both practical and well-positioned for dissemination.

Contents

1. **Study Participation** – A worksheet for integrating burden-reduction strategies into study design.
2. **Communication/Dissemination** – A planning tool for communicating study results to patients and families.

**References:**

1 <https://www.pcori.org/sites/default/files/PCORI-Guidance-Design-and-Conduct-of-Trials-Real-World-Settings-Factors-to-Consider-Pragmatic-PCOR.pdf>

2 <https://www.pcori.org/research-related-projects/about-our-research/returning-study-results-participants-important-responsibility>

## Reducing the Burden of Study Participation Worksheet

**Instructions:** This worksheet helps integrate strategies to reduce time, emotional, logistical, and medical burdens on PFIC patients and families participating in your study. As before, these ideas were developed through Project IMPACT and reflect what the PFIC community identified as important for supporting participation in patient-centered CER.

🖱️: ̗̀➛ *IMPACT Roadmap Section:* [*https://impactroadmap.pfic.org/strategies-to-reduce-the-burden-of-study-participation/*](https://impactroadmap.pfic.org/strategies-to-reduce-the-burden-of-study-participation/)

**Create a trusted and welcoming environment**

|  |  |  |
| --- | --- | --- |
| **Strategy** | **Planned?** | **Notes/Implementation Plan** |
| A strong recommendation from a trusted physician | ☐ | *Example(s): share study information with local physicians* |
| Mental health or psychological support if needed | ☐ | *Example(s): offer participants 1:1 sessions with psychologist*  |
| A dedicated case manager or care coordinator | ☐ | *Example(s): assign a single point of contact for each family to assist with scheduling, transportation support, and follow-up needs* |
| A communication specialist trained to answer questions | ☐ | *Example(s): provide a research liaison available by phone/email to explain study details in plain language* |
| Friendly, welcoming research staff | ☐ | *Example(s):* *train research staff in trauma-informed and culturally sensitive approaches* |
| Personalized reminders | ☐ | *Example(s):* *send appointment reminders via text or phone call tailored to each family’s preferred method and language* |
| Toys, activity kits, or gifts for child participants | ☐ | *Example(s):* *offer age-appropriate items (e.g., coloring kits, small toys, gift cards) to keep children engaged and reduce anxiety during visits* |

**Time & Compensation**

|  |  |  |
| --- | --- | --- |
| **Strategy** | **Planned?** | **Notes/Implementation Plan** |
| Limit time required away from home or family | ☐ | *Example(s):* *schedule consolidated appointments or use telehealth for follow-up visits* |
| Offer services at home or local clinics | ☐ | *Example(s): partner with regional clinics or provide home nursing visits for routine labs or check-ins* |
| Minimize number of hospital visits required | ☐ | *Example(s): combine multiple study procedures into a single visit when possible* |
| Provide financial compensation | ☐ | *Example(s):* *compensate per visit to offset travel and time costs* |
| Flexible timing of visits | ☐ | *Example(s): allow evening or weekend options to accommodate work and school schedules* |
| Scheduling visits during breaks from school to minimize disruption | ☐ | *Example(s):* *plan visits during school holidays or summer break* |
| Shorter visits | ☐ | *Example(s): streamline procedures to reduce wait time and keep visits under 2 hours* |

**Medical & Other Considerations**

|  |  |  |
| --- | --- | --- |
| **Strategy** | **Planned?** | **Notes/Implementation Plan** |
| **Medical** |
| Minimize medical trauma anticipated | ☐ | *Example(s): use numbing cream or gas protocol for injections and child life specialists to provide support during procedures* |
| Avoid invasive procedures when possible (e.g., use surveys) | ☐ | *Example(s): replace liver biopsy follow-ups with imaging and patient-reported outcome surveys when clinically appropriate* |
| Do not require blood draws beyond routine care | ☐ | *Example(s):* *align study labs with standard clinical visits* |
| **Other**  |
| Frequent updates on study progress, changes, and results | ☐ | *Example(s):* *send participants quarterly newsletters in plain-language*  |
| A transparent plan for dissemination of study results | ☐ | *Example(s): share results through webinars, lay summaries, and infographics posted on the study website and sent to participants* |
| Set clear expectations | ☐ | *Example(s): provide a one-page overview outlining study procedures, visit frequency, and participant responsibilities upfront* |
| Allocate support for smaller centers to enroll study participants | ☐ | *Example(s):* *provide extra staff training, remote monitoring, and funding for part-time study coordinators at smaller sites* |

## Communication & Dissemination Planning Tool

**Instructions:** This planning tool can be used to plan how PFIC patients, families, and other stakeholders are kept informed throughout the research process. Participants in Project IMPACT emphasized the importance of timely, accessible updates and clear communication of study findings. The prompts below are based directly on their feedback.

🖱️: ̗̀➛ *IMPACT Roadmap Section:* [*https://impactroadmap.pfic.org/communication-dissemination/*](https://impactroadmap.pfic.org/communication-dissemination/)

**Communication Channels**

Which of the following channels are going to be used to communicate study information and results to patients and other stakeholders?

👉 IMPACT participants preferred email newsletters and website updates most.

|  |  |  |
| --- | --- | --- |
| **Channel** | **Planned?** | **Frequency/Use Notes** |
| Email newsletters | ☐ | *Example(s): send quarterly updates with study progress or results* |
| Website updates (e.g., PFIC.org) | ☐ | *Example(s): post lay summaries, FAQs, and downloadable study materials*  |
| Social media | ☐ | *Example(s): biweekly posts with visuals, short captions, and links to resources (e.g., recruitment info, event reminders)* |
| Live webinars | ☐ | *Example(s): launch, mid-point, and closing webinars with Q&A sessions; recordings shared for those who can’t attend live* |
| Print mail (e.g., postcards or summaries) | ☐ | *Example(s): annual mailed summaries with key findings and next steps, using clear language and graphics* |
| Academic publications | ☐ | *Example(s):* *peer-reviewed publications accompanied by lay summaries emailed or mailed to participants and posted online* |

**Dissemination Strategies**

How will study information be shared with patients and stakeholders in clear, accessible ways?

|  |  |  |
| --- | --- | --- |
| **Strategy** | **Planned?** | **Notes/Implementation Plan** |
| Provide study updates and results in plain language | ☐ | *Example(s): share quarterly updates written at a 5th-grade reading level* |
| Offer updates and results in visual or multimedia formats  | ☐ | *Example(s): create infographics summarizing findings and 2-minute video explainers with voiceover* |
| Break longer materials into short, navigable segments  | ☐ | *Example(s): use chaptered video updates (e.g., “Results,” “What It Means,” “Next Steps”) with clickable timestamps* |
| Assign a consistent point of contact participants can reach out to with questions | ☐ | *Example(s):* *designate a study coordinator’s email and phone number, introduced during enrollment and included in all communications.* |
| Centralize study information and results in a publicly accessible place  | ☐ | *Example(s): host a study page on PFIC.org with downloadable materials, FAQs, and updates* |
| Acknowledge and/or demonstrate how patient & stakeholder input shaped the study | ☐ | *Example(s):* *include “You Spoke, We Listened” sections showing how patient input led to changes (e.g., reduced visits, added outcomes)* |
| Continuously gather feedback on whether communication was clear and useful | ☐ | *Example(s):* *add short post-update surveys asking if information was understandable and what else participants want to know* |