Patient Centric Trials
ICR Forum 6th September

Tom Ruane
Global Head, Patient Recruitment
September 2019
Patient-Centric Design: Impact

19% more likely to launch Investigational treatment

Phase II and III likelihood of launch for patient-centric trials vs. all trials

All therapy areas Neurology Oncology Rare diseases

0% 20% 40% 60% 80% 100%

Approximately 40% shorter recruitment period

Average time to enroll 100 participants for patient-centric trials vs. all trials (months)

Rare diseases Oncology Neurology

0 5 10 15 20 25 30 35

All trials Patient-centric trials

Data: 2012-2017. Source: Trialtrove® | Pharma Intelligence. © 2018 The Economist Intelligence Unit Ltd. All rights reserved. © 2019 Parexel International Corporation
Patient-Centric Design: Impact

Only 1 out of 20 studies included a patient-centric design.

Adoption rates of selected innovations*

<table>
<thead>
<tr>
<th>Innovation</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptive trial design</td>
<td>0.6%</td>
</tr>
<tr>
<td>Patient-centric</td>
<td>5.2%</td>
</tr>
<tr>
<td>Precision medicine</td>
<td>13.7%</td>
</tr>
<tr>
<td>Real-world data</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

* Innovation adoption rate is defined as the number of Phase II & Phase III trials indicating use of innovation during the above period, as percentage of trials where innovations were not present from the same period of time.

© 2018 The Economist Intelligence Unit Ltd. All rights reserved.
© 2019 Parexel International Corporation
Patient as a stakeholder – the evolution of personalised medicine

1992

General Practice & Primary Care

2002

Payers / providers

2008

Patient Advocacy

2010

Hospitals & Specialist Physicians

2005

2008

2016

The Patient
Simplify the patient journey

- Design around patient needs
- Improve relevance and convenience to participate
Using language & images the patient relates to...

**EDUCATE / ENGAGE**
- Websites, Digital Banners,
- APPs Study Posters and Flyers

**CONSENT / RANDOMISE**
- iPad, ICF Flip Charts, Consent+ Aid tools
- APPs & Digital Study Brochures, Dear Patient Letters

**PARTICIPATION / VISITS**
- Visit by Visit Study Guides
- Study Fact Sheets, Appointment Reminder cards, and Compliance Aid Tools

**COMPLETION**
- Greater Gift - Thank You and Appreciation Cards
- Patient & Study Alumni, End of Study Lay summaries
How many steps removed is the patient relative to each study?

PATIENT / DISEASE SUPPORT GROUPS
Local awareness & engagement campaigns

RADIOGRAPHY DEPT.
Assessing the links and relationships with all other members of the MDT, incl. CT, MRI, PET etc.

SURGICAL UNIT
Setting up patients effectively for i.e. Biopsy, lumpectomy etc.

GENERAL MEDICINE
Patients presenting with early symptoms, or flare etc.

ONCOLOGY OUTPATIENT CLINIC
Understanding patient motivation during the different stages of treatment

PHARMACY
Looking at proxy medications on repeat Rx as patient source

PRIMARY CARE
Mild or asymptomatic patients managed in primary care, several steps from site

Specialist Nurse Teams
Macmillan, Marie Curie, etc. Providing information on studies involving nurses & patients.
Dealing with innovation – at the inflection point

Agreeing Scope and de-risking the deployment:

- Eye always on the deliverable – randomised patients!
- Keep it simple for patients and sites
- Scope set jointly between using probability scoring for risk
- Negotiating risk based agreements with vendors on
- Risk assessment and de-risking inclusion of innovation tactic on a study
Mapping the patient pathway from insights – virtual studies

**Patient Insights & Burden Analysis:** Understand patient study burden to assist trial strategy creation

**Pharmacy outreach:** Virtual trial recruitment via pharmacist network

**Patient Recruitment and Retention (PRR) platform:** Online study education and screening

**eConsent:** Online study consenting

**Home nursing:** Study tests/procedures provided in the patient’s home

**Direct-to-Patient (DTP) drug shipments:** Study drug/device delivered direct to the patient’s home

**Patient app:** Study information and support provided on patient’s own/provisioned smartphone

**Patient transportation:** Providing practical/financial support for travel to clinic

**Social Media Outreach:** Analytics, influencers/bloggers - recruitment via social media advertising

**Sensors:** Continuous monitoring of patient health outcomes

**Electronic Clinical Outcomes Assessment (eCOA):** Patient/caregiver reports health outcomes directly on a smartphone

**Telemedicine Visits:** Virtual study visit using video calls through the patient’s smartphone

© 2019 Parexel International Corporation
Informed consent
Decoding the clinical trial – the IBD / IBS lesson…
Informed consent with animated video

- Video
- Models
- Animations
- Algorithms running behind video
- Comics for children
- eCONSENT
Informed consent with animated video

Making an informed decision

- Identify potential patients
- Show animated video
- Discuss with patient
- Patient consents to join study

Consult with family members
Virtual trials
Taking the study to the patient
What are virtual trials?

Virtual/remote/decentralised/site less trials (Ph I-III) or direct-to-patient (DTP) /direct-with-patient (DWP) studies (Ph IV) are designed to make it as easy as possible for patients to participate in clinical research by **taking all or part of the study to them in their homes**
Why virtual trials?

There are currently >40,000 clinical studies recruiting in the U.S.

80% delayed due to recruitment problems*

70% of potential participants live more than 2 hours away from their nearest study center, which limits recruitment and retention**

85% of clinical trials fail to retain enough patients

30% average dropout rate across all clinical trials***

The plan is to make studies more accessible by deploying a virtual trials service to reduce the practical, financial and geographical barriers to participation, thereby achieving better recruitment and retention.


© 2019 Parexel International Corporation
Virtual visit

- Site portal
- Patient portal
- Home nurse support
- Telehealth visit
Virtual trials
Home nursing
Ensuring Good Clinical Practice (GCP)

Investigator responsibilities

- Responsible for decisions and involved
- Adequate staff and facilities
- Collaborate with home nurses
- Data integrity (accuracy, completeness, timeliness)
Simplify the patient journey
So, what does it all mean?

- Face-time with doctors, self-diagnosis and on-line pharmacy
- UBER Health, Google health, 23andMe
- Isolation of patients (MDD) and some actually not wanting nurses to visit them at home
- Doctors & Nurses air traffic controllers of patient care – ask them at Feasibility
Thank you