Transforming the clinical trial patient experience

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Accenture Interactive

Clinical development is challenged by many factors and the current situation has compounded the issue

It looks like running a hurdle race

Low patient retention

30% average dropout rate across all clinical trials and **85%** of clinical trials fail to retain enough patients*.

* Forte Research Systems - http://forteresearch.com/news/infographic-retention-in-clinical-trials-keeping-patients-on-protocols/

High cost impact

$2.6bn cost of developing a prescription drug that gains approval*.

* Tufts Center for the Study of Drug Development - Profiles of New Approaches to Improving the Efficiency and Performance of 3. Pharmaceutical Drug Development, 2015

Delayed analytics capabilities

62% clinical researchers do not have real-time access to all of their clinical trial data*.

* Adaptive design clinical trials: a review of the literature and ClinicalTrials.gov (2017)

Poor data capture & quality

58% clinical researchers are not confident in data quality from an audit perspective*.

* Challenges And Opportunities: In Clinical Data Management (2018)

Lack of real-time continuous monitoring

99% patient health-related activities happens outside of hospital or clinic*.

* Wearables in Clinical Trials (2019)

Low recruitment efficiency

20% of investigators fail to enroll a single patient and **30%** under enroll in a given trial.

* B.Spiker and J.A. Cramer, Patient Recruitment in Clinical Trials (Raven Press, New York, 1992)

While facing the wind

COVID-19 brought another layer of complexity

Non-COVID-19 clinical trials are challenged. This may impact nearly **7.5 million patients** targeted for enrollment in 15,000 trials, currently registered or in flight.*

Research estimates that in the next **6 months**, 6,500 trials and **1 million patients may be affected**.*

In response to COVID-19 pharma companies must shift their focus across their trials and pipelines to mitigate risk to more than 300 pivotal trials and subsequent loses of more than **$20 billion**[2].

Total risk of disruption: Estimated impact on registered, in flight and upcoming trials*

~21.5K

Trials

>8.5M

Patients

*Source: Accenture Research and Evaluate Pharma Database Analysis

1. Accenture Research in Collaboration with Informa Pharma Intelligence
2. Accenture Research and Evaluate Pharma Group Database of Forecasts and Estimates

Which is only a part of the full picture

Patient experience is an afterthought	**90%** of eligible patient population are not aware of available clinical trials	**35%** of patients drop out of trials due to lack of patient-centric design	**40%** of patients becoming non-adherent to investigational medical products after **150 days**
Management process is overwhelming	Compared to 2001-05, the average number of data points have increased by **88%**	Trial procedures have increased by **65%**	**77%** of sponsors and CROs have difficulty with loading patient data due to compatibility and integration challenges

Sources: Pharmafocus: Clinical Trial and their Patients: The Rising Costs.and How to Stem the Loss, Contemporary Clinical Trials. Clinical trials recruitment planning: A proposed framework from the Clinical Trials Transformation Initiative, Tufts Center for the Study of Drug Development: Impact Reports July/August 2018, Vol. 20 No. 4 Tufts Center for the Study of Drug Development: Impact Reports Jan/Feb 2018, Vol. 20 No. 1, *Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary. Washington (DC): National Academies Press (US); 2010. 6, Clinical Trials in Cancer. Available from: https://www.ncbi.nlm.nih.gov/books/NBK50895/, ** National Institute for Clinical Research Network (NIHR CRN) Survey 2014. https://www.nihr.ac.uk/news/nine-out-of-ten-people-would-take-part-in-cl... Challenges And Opportunities: In Clinical Data Management (2018), Center for Information and Study on Clinical Research Participation (CISCRP) (2017), Adaptive design clinical trials: a review of the literature and ClinicalTrials.gov (2017)

It's time to make actual changes that benefit the patient long-term

Adopting a human centric approach to deliver tangible patient and ultimately business outcomes

Value Levers	Metrics	Value Type
Improve participant-centricity	• Reduced time taken to recruit patients • Reduced patient drop out rate (and related trial delays) • Reputation gain	
Real-time availability of better quality data	• Reduced "Drug Lag" (time between regulatory submission and approval) • Improved value proposition to healthcare systems and payers • Faster success or failure rate (phase by phase)	
Increase productivity of clinical trial execution	• Improved workforce productivity of existing R&D staff • Improved cross BU communication rates • Reduced average (vendor) cost per patient (trial staff and site monitoring)	

Key — Increased Efficiency — Decreased Cost

So… How do we move toward a participant centricity clinical development process?

It begins with understanding the needs of the stakeholders…

We need to take multiple stakeholders into account in order to transform the clinical trial paradigm

Patients put themselves and their values at the heart of the decision process.

- Widen treatment options
- Improve quality of life
- Be part of the decision
- Smart and easy
- Rewarded for efforts
- Self-care

Investigators put the patient and scientific progress at the center of the decision process.

- Furthering clinical research
- Access to novel treatment options
- Increase reputation
- Optimize resource
- Acquire new knowledge gain
- Challenge the status quo

Sponsors put developing new and safe treatments for patients and the future of the company at the forefront of the decision process.

- Investigate new treatment options
- Ensure safety and efficacy
- Stay ahead of the competition
- Optimize resource
- Increase reputation
- Build strong relationships with KOLs

However there is an intention to action gap;

engaging these stakeholders remains the biggest barrier to optimized clinical trials

+90% of patients would like to participate in medical research*, but only around 3% of patients ever do**

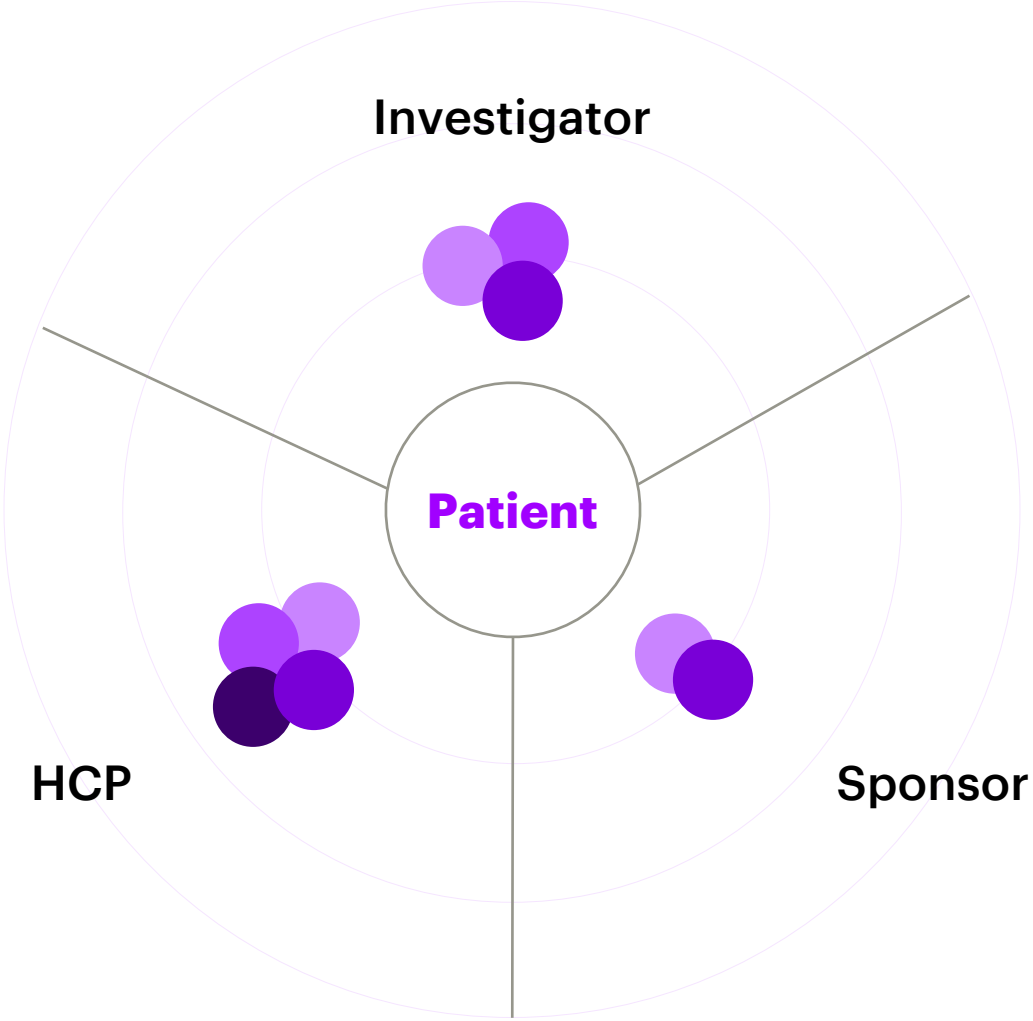
+20% of investigators fail to enrol a single patient and 30% under-enrol in a given trial

+19% of studies close or terminate early because they could not accrue enough patients

* Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary. Washington (DC): National Academies Press (US); 2010. 6, Clinical Trials in Cancer. Available from: https://www.ncbi.nlm.nih.gov/books/NBK50895/
** National Institute for Clinical Research Network (NIHR CRN) Survey 2014. https://www.nihr.ac.uk/news/nine-out-of-ten-people-would-take-part-in-cl...

The strain is creating tension in the patient experience

- **Access:** Inclusion and exclusion criteria creates a barrier to care
- **Relationship:** Its difficult for the HCP to build a long term understanding of the patient
- **Confusion:** Harder to know clinical trials options
- **Alienation:** Patients are left unsupported tackling an emotive and sensitive challenge



Let’s be more specific… meet Jill

She was diagnosed with **Multiple Sclerosis** 2 years ago and she is on standard interferon treatment. She is treatment adherent and can manage her side-effects, even though they are severe at times.

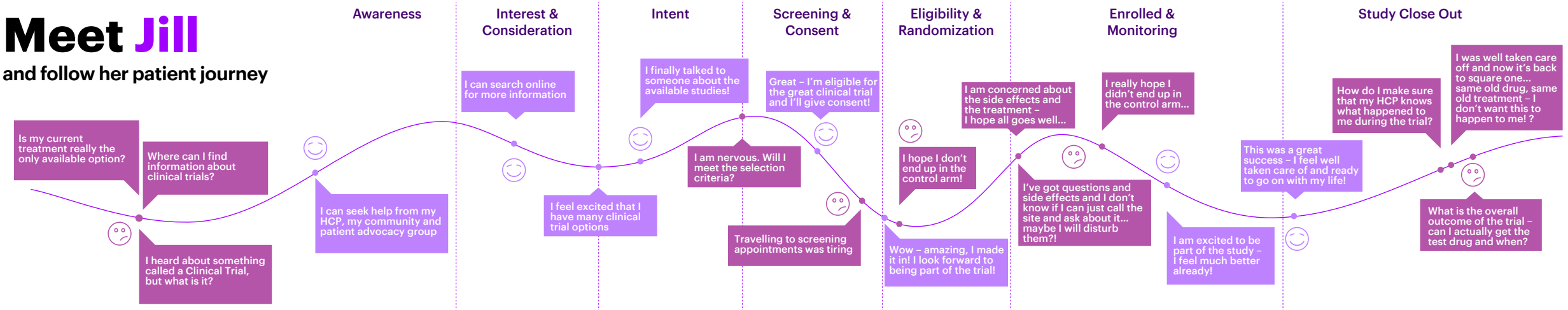
She suffered a relapse and starts to question the efficacy of her current drug.

She recently heard about an ongoing clinical trial during one of her MS support group meetings and she wonders if this would be a viable option for her as well.

Even though she is actively involved and engaged in managing her health she encounters several hurdles along the way…

Meet Jill

and follow her patient journey



Gaps

Delayed understanding of trial setup
Improper onboarding of clinical trial setup, design, risks and benefits can compromise the recruitment process

85%
of patients may not be aware clinical trials exist at all

40%
of patients interested in clinical trials agreed that a suggestion tool would help them find clinical trials*

Less than one in 20
know how to find out more about clinical trials

Less than 10% of patients who start a pre-screener randomize into a study trial.
The consent form is long, and written in medical language
Caregiver's concerns are not addressed

80% of clinical trials fail to meet enrolment timelines
Friends & Caregiver concerns

1 out of 3 of Phase III clinical study termina-tions are due to **enrolment difficulties.**

Different hospitals treating the same patient may **not use the same EHR software to enter data**.
Many clinical studies still rely on **paper diaries** instead of an electronic system
Medication adherence tracking is prone to human error

Poor handover between investigator (CT) and HCP (follow on treatment)
Treatment gap – higher site/patient interaction during CT
No updates and interaction regards next steps (approval/ rejection of investigational compound) and study outcomes

Opportunities

Netnography research about patient's previous trial experience
Adopt participatory methods to enable patients and medical staff to provide input on protocols
Gather feedback from regulators or payers on existing protocol design weaknesses

Increase HCP awareness and provide access to education
Incorporate social listening to gather HCP and patient insights
Placement of Search Engine Ads, digital ads and TV ads and activation of social media engagement

Provide educational material in the form of a blog, patient stories and doctor stories
Empower, Patients, Patient groups and HCPs with the right information

Captures user information for future trials
Redirect patient to another pharma company's trial
AI to automate clinical trial matching
Trial finder with Online pre-screening

Provide visibility of consent information and other trial information before in clinic screening
Utilize communication touchpoints such as live chat, chat bots, phone line or video calls to connect and engage participants

Provide materials to educate employers/ family members
Support patients emotionally and with logistics: Make them feel valued and supported throughout enrollment process

Unified Tracking System
Connected devices for accurate real time monitoring
A companion app can increase adherence by alerting patients to their appointments

Trial appointments should fit around work schedule
Site visits could affect childcare needs

Capture of non-trial confidential materials and information in easy to share format(e.g. eDiaries, etc.)
Easy to access comms lines (chat, phone, video, etc.) between investigator and HCP
Use apps to push out informational content to 'ex-study participants' once patient completed study

Design a Human Centric Clinical Trial	Recruitment for Clinical Trial	Enrollment & Onboarding	Monitoring & Adherence	Close Out & Hand Over

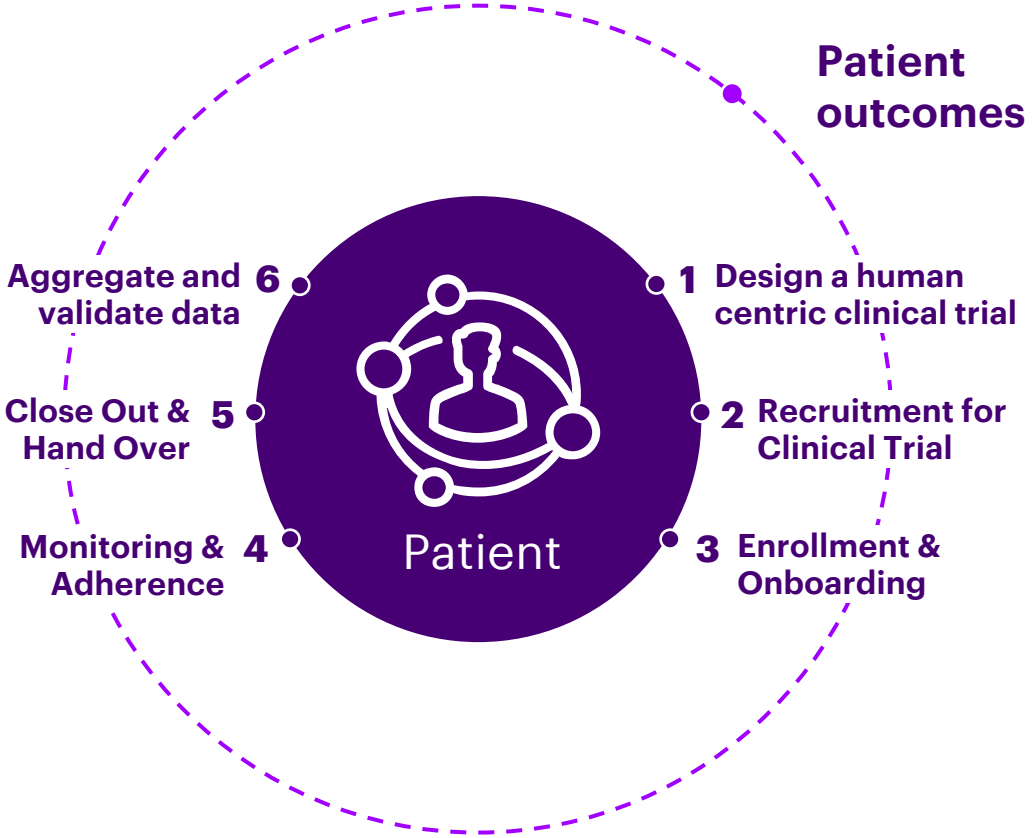
Service Design, Data Analytics, Creative Design, Content Management, Content Development, Ethnographic Research User Experience Design, Innovation led design, Platforms and Technology, INTIENT

One size fits all drug development stakeholder engagement strategy is no longer applicable

We have created a modular framework that accounts for specificities...

We meet you where you are! Your journey is our journey...

We move the needle from a siloed journey to a more integrated patient centric ecosystem



We have designed
3 levels of support
to match your needs

+++ Urgent -

Booster

Targeted action to boost recruitment and/or ensure adherence

Focus

A one off experience strategy dedicated to optimize the clinical experience for a specific study

Holistic

We look at your online ecosystem and clinical trial portfolio and we offer a global strategy to offer a tailored and consistent experience for all your clinical trial

And deliver what you need at that moment

+++ ← Urgent → -

	Booster	Focus	Holistic
	...If you are short with time the **Booster** can be activated	...If you have a specific need the **Focus** can be activated	...If time is not of the essence a **Holistic** approach can be implemented
Action	Ethnographic research Gap Identification & Insights Media optimization Recommendations Patient journey mapping KPIs Content strategy Campaign strategy Campaign assets	Netnographic research Ethnographic research Patient segmentation Profile & Personal creation Physician data segmentation Social media targeting strategy Targeted campaign strategy Content & Asset production Data analysis & Performance report	Insights and Opportunity mapping Clinical study enrollment pathway Audience strategy Multichannel mix Promotion strategy Communication campaign
Business Impact	Increased net new participants Improved leads quality Lowered adherence drop off Increased revenue	Increased speed to trial start Reduced patient dropout rate Improved participant satisfaction Lowered adherence drop off Increased revenue	Improved investigator satisfaction Improved participant satisfaction Increased final screening success rate Improved compliance & adherence to protocols Improved data collection

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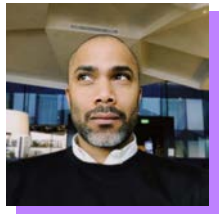

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