



# Building Patient-Centric Trials

## *Putting the Patient First*

July 17, 2019

# Agenda

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Welcome and Introductions	10:00 am to 10:05 am
The Need for At-Home Trials and Nurse Care	10:05 am to 10:25 am
Home Trial Support Drives Patient Centricity	10:25 am to 10:45 am
Q&A	10:45 am to 11:00 am

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**Annick Anderson**, *Director of Research Services at CISCRP*



**Helena Baker**, *Vice President of Clinical Strategy at MRN*

# The Need for At-Home Trials & Nurse Care



# Trends in Protocol Design Practices

<i>Typical Phase III Pivotal Trial (means)</i>	<b>2001 - 2005</b>	<b>2011-2015</b>	<b>Change</b>
<b>Total Number of Endpoints</b>	<b>7</b>	<b>13</b>	<b>86%</b>
<b>Total Number of Eligibility Criteria</b>	<b>31</b>	<b>50</b>	<b>61%</b>
<b>Total Number of Distinct Procedures</b>	<b>22</b>	<b>35</b>	<b>59%</b>
<b>Total Number of Procedures Performed</b>	<b>110</b>	<b>187</b>	<b>70%</b>
<b>Total Number of Planned Volunteer Visits</b>	<b>12</b>	<b>15</b>	<b>25%</b>
<b>Proportion of Data that is 'Non-Core'</b>	<b>18%</b>	<b>32%</b>	<b>78%</b>
<b>Number of Investigative Sites</b>	<b>40</b>	<b>65</b>	<b>63%</b>
<b>Number of Countries</b>	<b>5</b>	<b>10</b>	<b>100%</b>
<b>Number of Patients Randomized</b>	<b>729</b>	<b>597</b>	<b>-18%</b>
<b>Total Data Points Collected</b>	<b>494,236</b>	<b>929,203</b>	<b>88%</b>
<b>Number of Data Collection Applications Used</b>	<b>2</b>	<b>6</b>	<b>200%</b>

*Source: Tufts CSDD*



**50%** fail to enroll a single patient or under enroll



average drop-out rate of **30%** across clinical trials

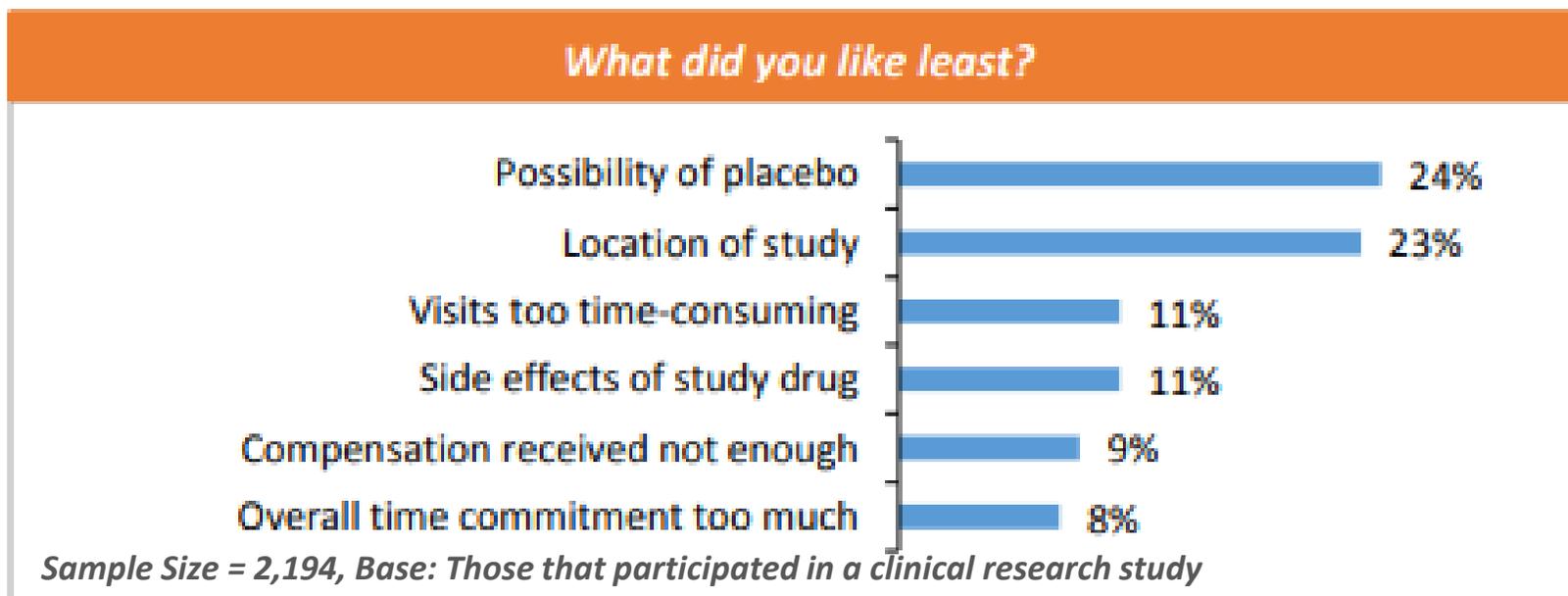
*Source: Forte Research, 2016*

*Source: Tufts CSDD 2017*

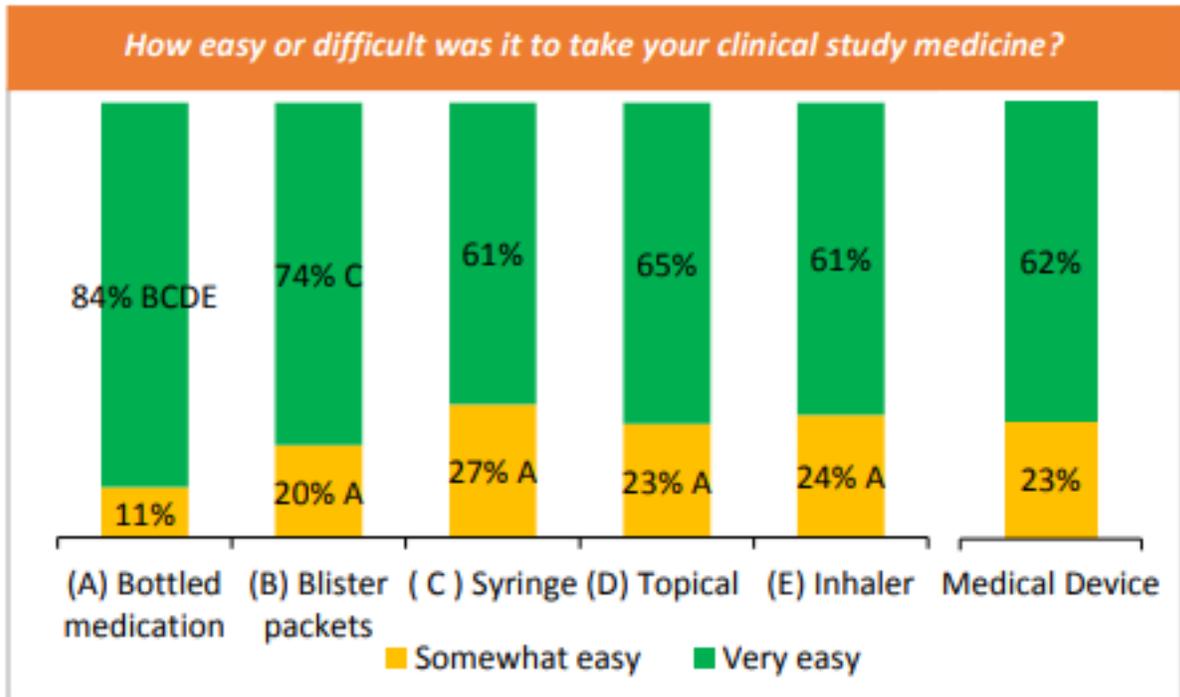
# Patient Participation Burden

<p><i>Top reasons participants decided to not take part in a clinical trial after reviewing ICF</i></p>	<p><b>TOP MENTIONS</b></p>	<p><b>Side effects scared me</b></p>	<p>29%</p>
		<p><b>Too many study visits</b></p>	<p>24%</p>
		<p><b>Medical procedures too invasive</b></p>	<p>18%</p>
		<p><b>Afraid of receiving placebo and too many medical procedures</b></p>	<p>14%</p>

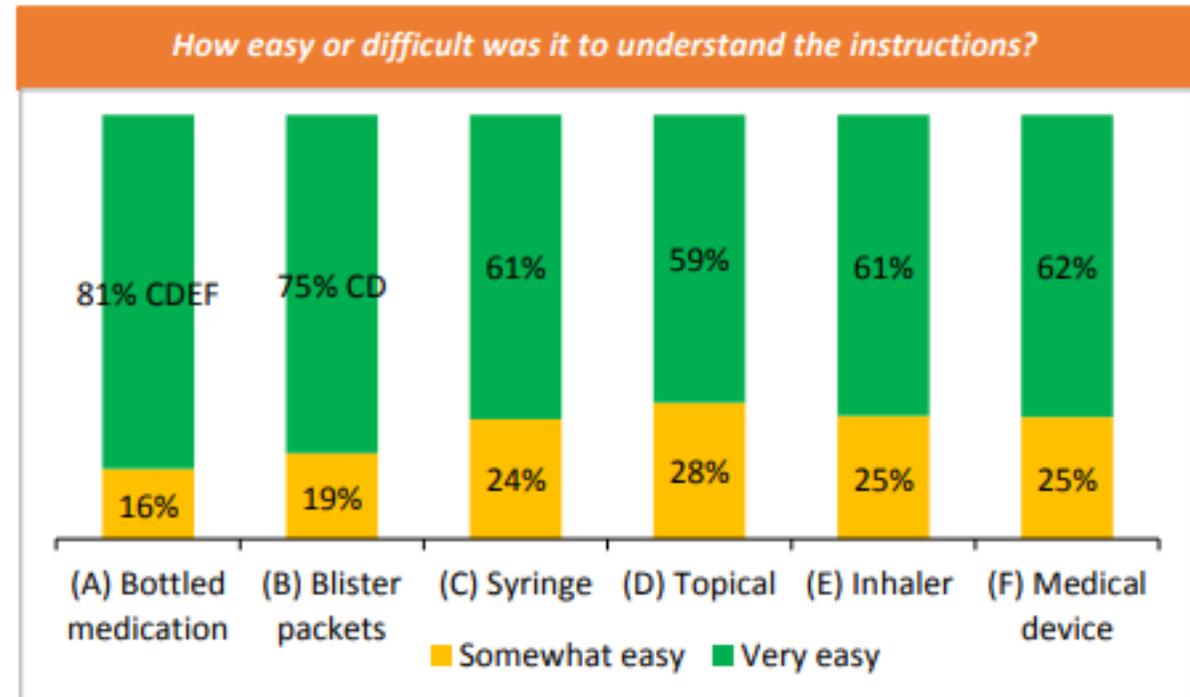
Sample Size = 337 Base: Those who have participated in a clinical trial but who reported having decided not to participate after reviewing an ICF



# Supporting Medication Administration



Sample Size = 1,248, Base: Those that received medicine/medical device \*Letters indicate statistical significance at the 95% CL



Sample Size = 1,248, Base: Those that received medicine/medical device \*Letters indicate statistical significance at the 95% CL

# What have we learned from patients?

## Patients want...

✓ Quality blood draws 

*“The thing that bothered me was the way she drew blood...The nurse would ask me to turn on all the lights, because she couldn’t see my veins. In my head, I’m like, ‘hold on, I’ve never had this before...you’re trying to find my veins with your eyes instead of your hands.’ And my sister, she’s a phlebotomist, she’s looking at [the nurse] like, ‘What are you doing?’”*

✓ Consistent staff 

*“It’s nice having the same person. You get to know them, you trust them. Having somebody different every time would be a little weird.”*

✓ Support for nurse 

*“I wish that [my nurse] had a little more help, because [equipment] is heavy, and sometimes she would be kind of struggling. You’re not supposed to help as much as you want to help because if you get hurt, then they get in trouble...”*

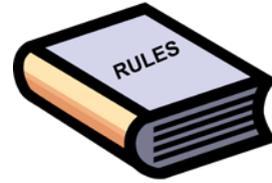
✓ Relationships 

*““My NP—my nurse practitioner—I love her. I’d rather see her than my actual doctor”...”*

# What have we learned from patients?

## Patients want...

- ✓ Established ground rules for in-home nurses



*"It was easy to talk to her and get along with [my nurse]. She made herself pretty sparse- you really didn't know she was there unless you heard the little machine going."*

- ✓ To meet all of these doctors at once to establish a "team"



*"During his post-transplant, we met the team of doctors. When you see this random doctor come in, you've seen them before, their face is familiar. So, you're like, OK, at least they're on the same team."*

- ✓ To store supplies in house, if space available



*"If I had the room, that would be totally fine. Some people have a really small space, but we're fine with putting [equipment] in the office."*

# Home Trial Support Drives Patient Centricity



# Why is “Patient-Centricity” important?

“For 2019, the trend of patient engagement is only likely to become more important with the continued desire for the patient to be involved in their own care”

Bradley, C (2019)

# Why is “Patient-Centricity” important?

## **Home versus outpatient administration of intravenous steroids for multiple-sclerosis relapses: a randomised controlled trial**

J Chataway et al. The Lancet Neurology - Vol 5 (7) Pages 565-571 July 2006

- *Concluded that clinical outcomes were the same or better in the group treated at home with no difference in safety, and that the cost of treatment in the home was the same or cheaper.*

## **Effectiveness of a Home Care Nursing Program in the Symptom Management of Patients with Colorectal and Breast Cancer Receiving Oral Chemotherapy: a Randomised, Controlled Trial**

A Molassiotis et al. Journal of Clinical Oncology - Volume 27 - Number 36 Pages 6191-6198 December 20, 2009

- *Concluded that significant improvements were observed in the home care group in various clinical parameters and that unplanned service utilization particularly the number of in-patient days was lower in the home care group.*

# A Patient Story - **Miranda**

- 35 years old
- Metastatic Breast Cancer patient
- 3<sup>rd</sup> line treatment
  - Choice:
    - Enter a trial at a large national teaching hospital 2 hours from home
    - Take the standard therapy option of Gem/Carbo
  - Chose the trial
    - The site staff weren't interested in Miranda
    - Staff were not interested in her symptoms beyond breast cancer
    - High study burden



**Miranda withdrew from the study**

# Trial Design – Accessibility

## Visit schedule

- **Get the invasive procedures done at the same time**
  - MRI's, CT's, Physical Exams must be done by site
  - ECG's, bloods, IMP admin can all be done at home
- **Think about the lab samples required – and when**
  - Do you really need those samples every week?
  - What sample handling is required?
- **Physician oversight**
  - Will the patient be seen at every visit by the PI?
  - If not, the visit may be suitable for homecare



# What can be done in the home?

## Simple Visits

- Vital signs
- Blood sampling
- Centrifugation
- Self administration training
- QOL
- Adverse Event capture/injection site reaction assessment
- Concomitant medication capture
- Nasal/Wound swabs
- Line care

## Complex Visits

- IMP Logistics
- PK draws
- IMP storage
- IMP reconstitution
- IMP administration
  - IV / IM / SC
- ECGs
- Spirometry

### And more...

*General rule of thumb:* anything a nurse can do independently with equipment that can be carried into the home.

# What are the benefits of home visits?

## For the Patient and their families:

- **Convenient, tailored care**
- Reduces travel burden
- Enables participation that otherwise may be prohibitive
- Comparative to normal standard of care (i.e. on a marketed product)



# What are the benefits of home visits?

## For the Clinical Research Site:

- **Convenient, tailored care for patients**
- Lessens burden on site staff
- Better site performance with increased patient recruitment and retention
- Wider recruitment net per site – more patients per site



# What are the benefits of home visits?

## For the Sponsor and CRO:

- **Convenient, tailored care for patients**
- Enhanced drug compliance
- Bigger pool of patients
- Advantage over other competing trials
- Get the product to market faster



**95%** Patient  
Retention Rate  
on Average



Increase in  
Patient Enrollment  
by **60%** on  
Average

# A Patient Story - Simon

- 15 years old
- Morquio Syndrome patient
- Situation
  - Trial requires him to receive weekly 5 hour infusions for 1 year
  - Referred to MRN for home trial support
  - Seen at site by home trial support nurse for introduction
  - Weekly home infusions and delivery of drug
- Simon:
  - Took his exams whilst receiving **Home Trial Support**
  - Completed the whole study with no missed visits



**Simon is now using home support post study through a commercial homecare provider**

# Questions?



**ANNICK ANDERSON**  
Director, Research Services  
CISCRP



+617-725-2750, x400



[annickanderson@ciscrp.org](mailto:annickanderson@ciscrp.org)



[ciscrp.org](http://ciscrp.org)



[Linkedin.com/company/ciscrp](https://www.linkedin.com/company/ciscrp)



[Twitter.com/ciscrp](https://twitter.com/ciscrp)



**HELENA BAKER**  
Vice President of Clinical Strategy  
Medical Research Network



+44 (0)1908 261 153



[enquiries@themrn.co.uk](mailto:enquiries@themrn.co.uk)



[themrn.co.uk](http://themrn.co.uk)



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