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# Patient Experience and Satisfaction with Electronic Consent, Onboarding, and Diaries in Clinical Trials

January 2024

SYNDICATED REPORT

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Life Science Strategy Group, LLC (LSSG) report authors draw upon extensive business, consulting and life science experience and backgrounds.

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Mr. Meyer has managed consulting engagements in a variety of areas including strategic planning, opportunity assessments, pricing analyses, forecasting, brand awareness and equity assessments, competitive benchmarking, positioning and messaging strategy and clinical trial benchmarking and analysis.

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# I. Study Background

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## Study Background

*In a clinical trial, patients go through unique processes, such as trial consent, onboarding, and randomization, before taking part in a number of clinical trial activities, which include keeping a patient diary. These diaries are critical to clinical trials as they capture data pertaining to Patient Reported Outcomes (PROs), including patient experience, symptoms, and adverse effects. On the patients' end, patient diaries also enable them to keep track of that information between appointments. Patient diaries can be paper or electronic, with electronic being on either a desktop/laptop or a mobile device, though all formats attempt to balance capturing relevant information for the trial and ensuring low complexity as to not impact the patient experience.*

*This landmark report includes 300 patients involved in 1-2 clinical trials within the last 2 years from the United States and Europe. It explores experiences with consent and onboarding (including randomization), along with preferences, areas of satisfaction, and potential future changes regarding patient diaries.*

*In the report, Life Science Strategy Group also provides commentary and interpretation of the data, which reflects than 30 years of experience consulting to many of the leading global biopharmaceutical companies, clinical development CROs, and CRO industry analysts.*

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### Methodology

*The primary research for this report was fielded via an internet survey in November 2024 and draws from three hundred (N=300) patients that have been enrolled in 1-2 clinical trials in the last 2 years from the United States and Europe.*

*All study participants were prescreened by LSSG and asked to provide information on their clinical trial experience, including trial consent, onboarding, randomization, and use of various clinical trial activities. One such activity is patient diaries, which was explored in depth by comparing electronic and paper formats. Electronic diaries, especially, were probed for positive and negative aspects, along with current and future elements to include. Lastly, preferences were obtained to inform future clinical trials.*

*To draw deeper conclusions, the data from this study was segmented by geography and age of patients, then compared with significance marked by differences  $\geq 15\%$ . LSSG also leveraged its experience and knowledge about the global biopharmaceutical and CRO industries to inform key findings.*

*All data analysis and reporting was performed by LSSG consultants.*

*Patients were classified into the following segments:*

- **North America (NA)** – Patients located in the United States and Canada
- **Europe (EU)** – Patients located in Europe
- **<60<sub>y/o</sub>** – Patients under the age of 60
- **$\geq 60$ <sub>y/o</sub>** – Patients 60 years old or over

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### Segmentation



## IV. Detailed Findings

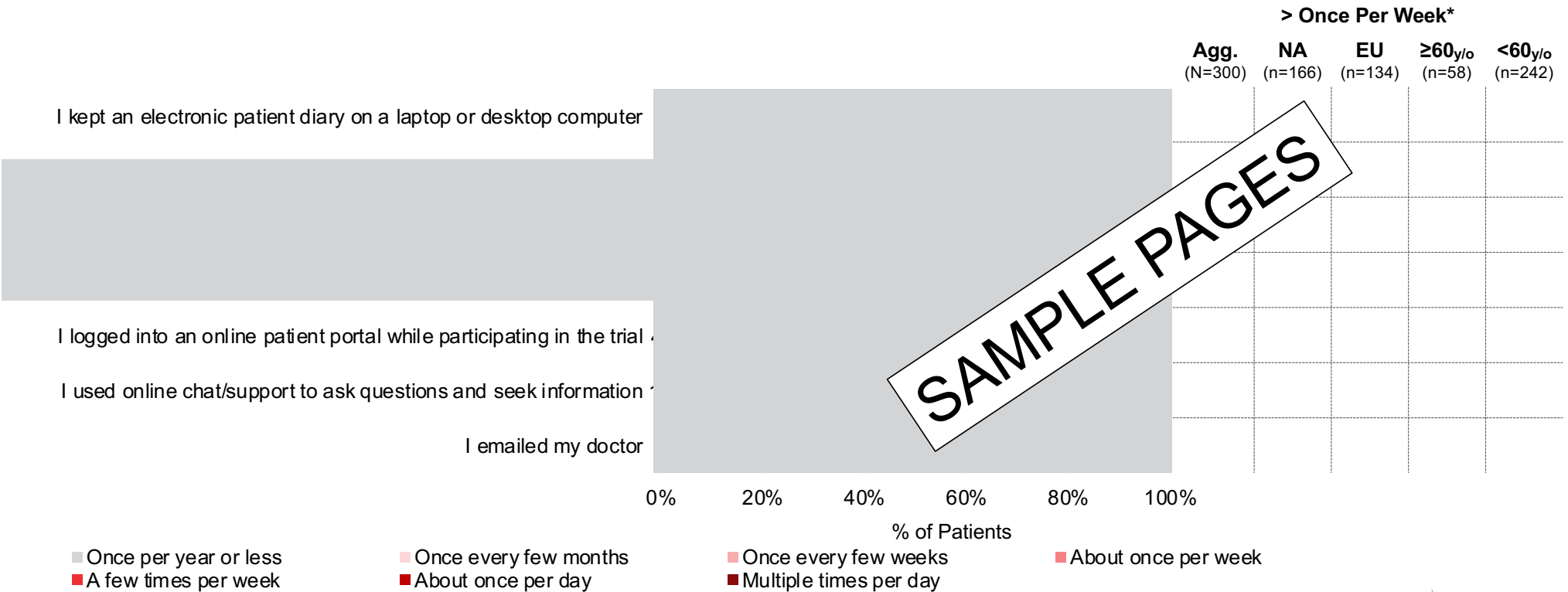
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On average, patients perform most clinical trial activities a XX, with those under 60 performing these activities YYYY.

### Frequency of Clinical Trial Activities

- Patients under xxxxxx (51% vs. 36%, respectively).



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Q1. How frequently did you complete each of the following activities during the trial?

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\*> Once per week = the sum of options A few times per week, About once per day, & Multiple times per day.

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The top opportunities to enhance clinical trial onboarding and randomization include X, Y and Z.

### Improvements to Trial Onboarding and Randomization\*

<u>Ways to Improve - Aggregate</u>
<ul style="list-style-type: none"><li>• [Redacted]</li><li>• [Redacted]</li><li>• [Redacted]</li><li>• [Redacted]</li><li>• [Redacted]</li><li>• [Redacted]</li><li>• Communication/Contact with the trial team (n=9)</li><li>• Convenience/Accessibility of trial visits (n=7)</li><li>• Compensation/Funding (n=6)</li><li>• More information on outcomes (n=6)</li><li>• More personable and engaged trial team (n=6)</li><li>• Less paperwork/forms (n=5)</li><li>• The procedure (n=5)</li><li>• Patient safety (n=4)</li><li>• Give more control to participants (n=4)</li></ul>

n=284

*"There was xxxxxx between being xxx... wing  
when exactly the trial would start."  
- North American Patient under 60*

*"The onboarding... it were **digital**."  
- North American Patient under 60*

*"... for the whole process to be xx and for  
to be yyyyyyy."  
- North American Patient under 60*

*"Just ..... for everyone to understand."  
- North American Patient 60 or over*

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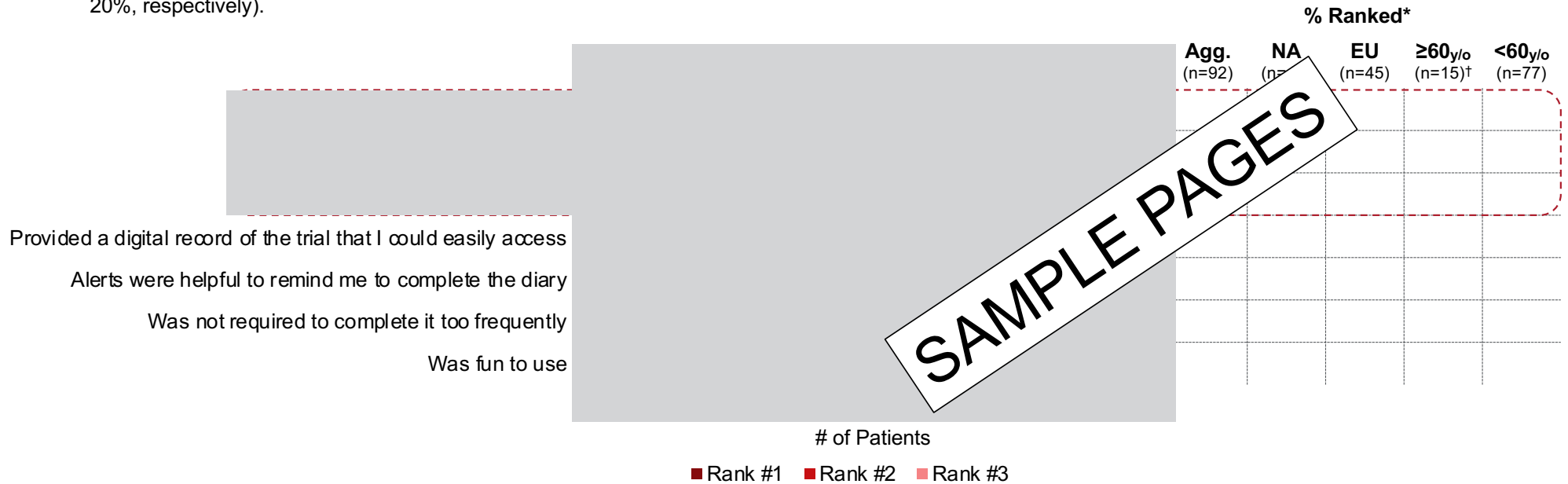
Q7. [Show if Q3b=1-5] What would you have liked to improve about the trial onboarding/randomization process?

\*Buckets with n>3 included.

Patients find X, Y, and Z to be key positive attributes. Those 60 or over are especially satisfied with ZZZ, while those under 60 also appreciate AAAA.

### Positive Aspects of Electronic Diaries

- North American patients find the ZZZZ to be a positive aspect more than European patients (68% vs. 47%, respectively); European patients BBBB to be a key positive aspect more than North American patients (56% vs. 28%, respectively).
- Directionally, patients 60 or over find
- GGG to be a positive aspect more than patients under 60 (87% vs. 58%, respectively); patients AAAA more than patients 60 or over (43% and 45% vs. 27% and 20%, respectively).



Other: it was interesting (n=1), it was simple to understand (n=1).

Q9. [Show if Q8c=1-5] What did you like about completing the electronic diary on your smartphone or tablet during the trial?

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\*\*% Ranked= the sum of those who ranked an option out of the total number of people seeing the question.

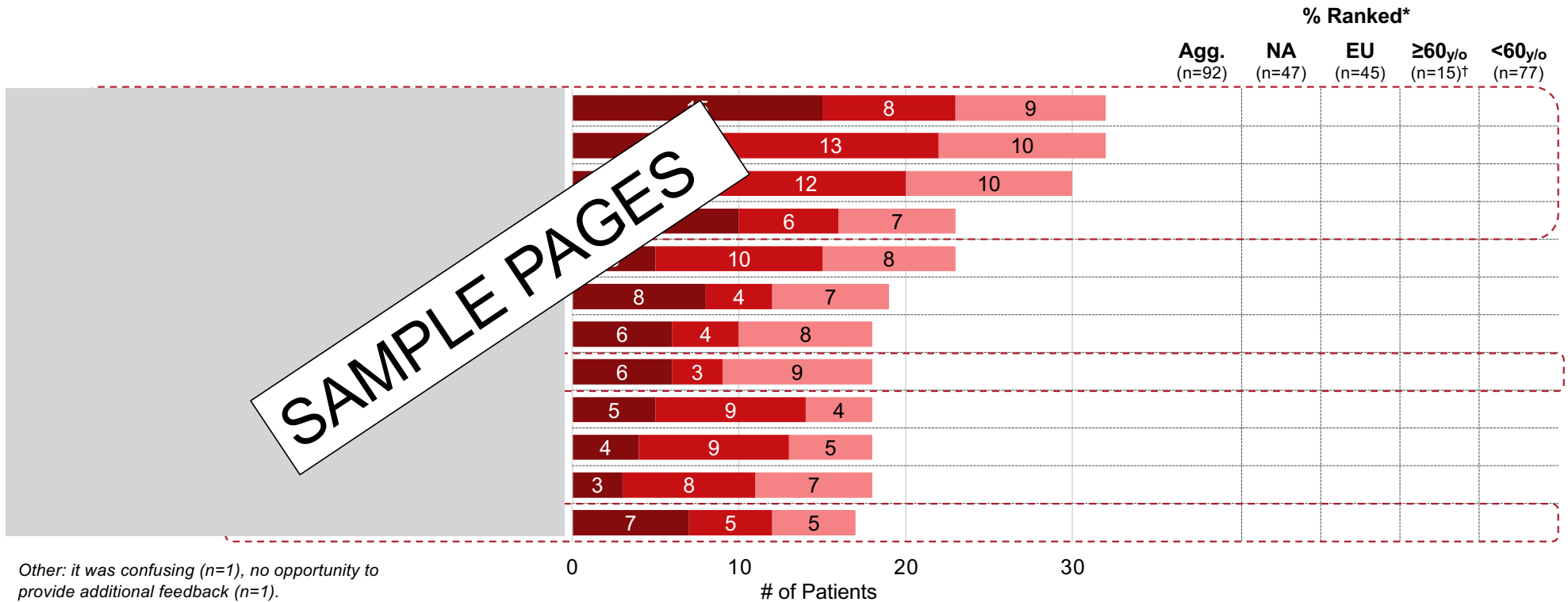
†Directional data.

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Patients note X, Y and Z and a lack of perceived value as leading negative aspects of electronic diaries. In addition to this, A also dislike the XXX, while some patients think the BBB could be improved.

### Negative Aspects of Electronic Diaries

- Directionally, more A than B dislike XXX (53% vs. 31%, respectively) and the YYY (33% vs. 17%, respectively).
- Directionally, more X and Y dislike the A and B (22% vs. 0%, respectively).



Q10. [Show if Q8c=1-5] What did you dislike about completing the electronic diary on your smartphone or tablet during the trial?

■ Rank #1 ■ Rank #2 ■ Rank #3

\*% Ranked= the sum of those who ranked an option out of the total number of people seeing the question.

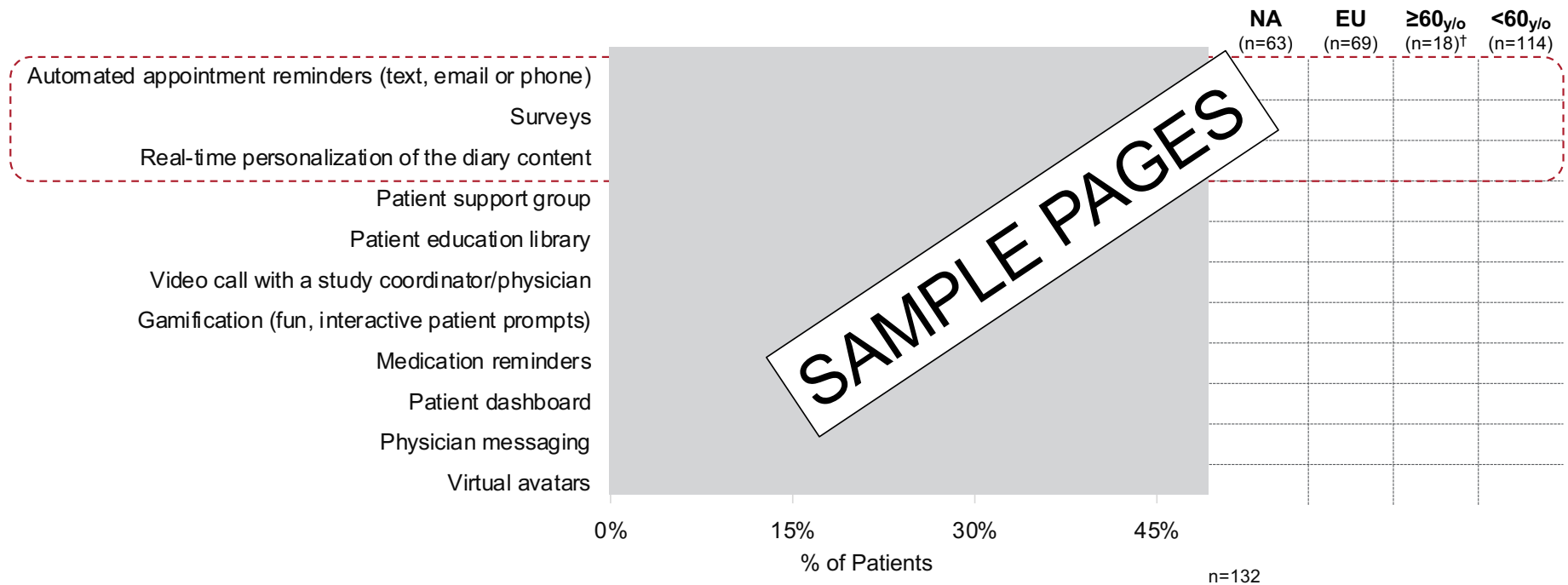
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Patients would like to X and Y in their electronic diaries, along with A and B content. Patients under 60 would like to see a Z more than patients 60 or over.

### Elements to Include in Future Electronic Diaries

- More European patients would like to see A and B in future electronic diaries than North American patients (43% vs. 27% and 41% vs. 22%, respectively).
- Directionally, more B and A suggest including AAA (39% vs. 17%, respectively), BBB (38% vs. 22%, respectively), video calls (37% vs. 22%, respectively), gamification (36% vs. 11%, respectively), ZZZZ (32% vs. 17%, respectively), and CCC (30% vs. 6%, respectively).



Q15. [Show if S10b or c selected] Which of the following elements would you like to see as part of your engagement/interaction with a future electronic diary?

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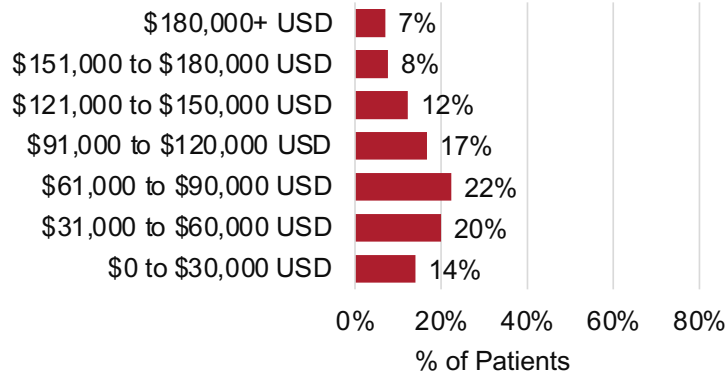
<sup>†</sup>Directional data.

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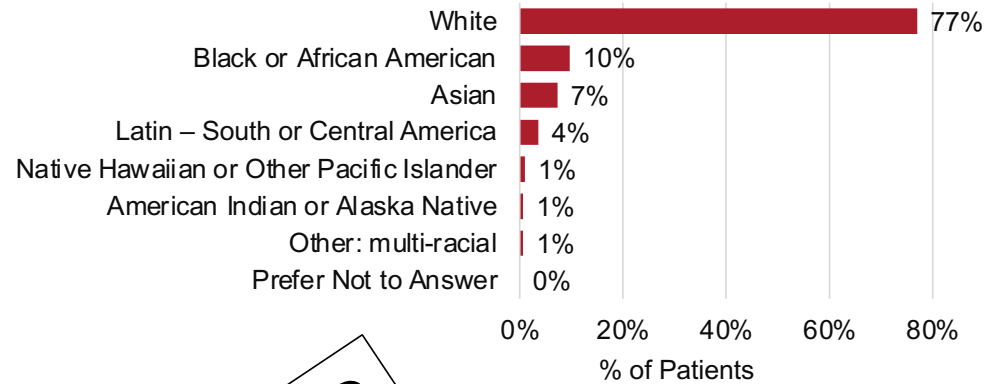
# Patient Demographics

- 55% of patients are located in North America and 45% in Europe.
- Across both regions, 53% live in urban areas, 35% live in suburban areas, and 12% live in rural areas.

## Total Household Income



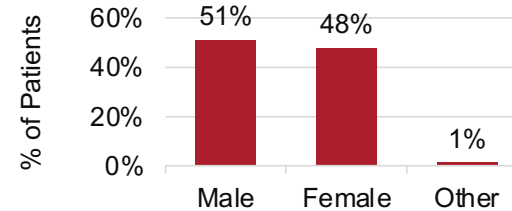
## Race & Ethnicity



## Age Range (Years)



## Gender



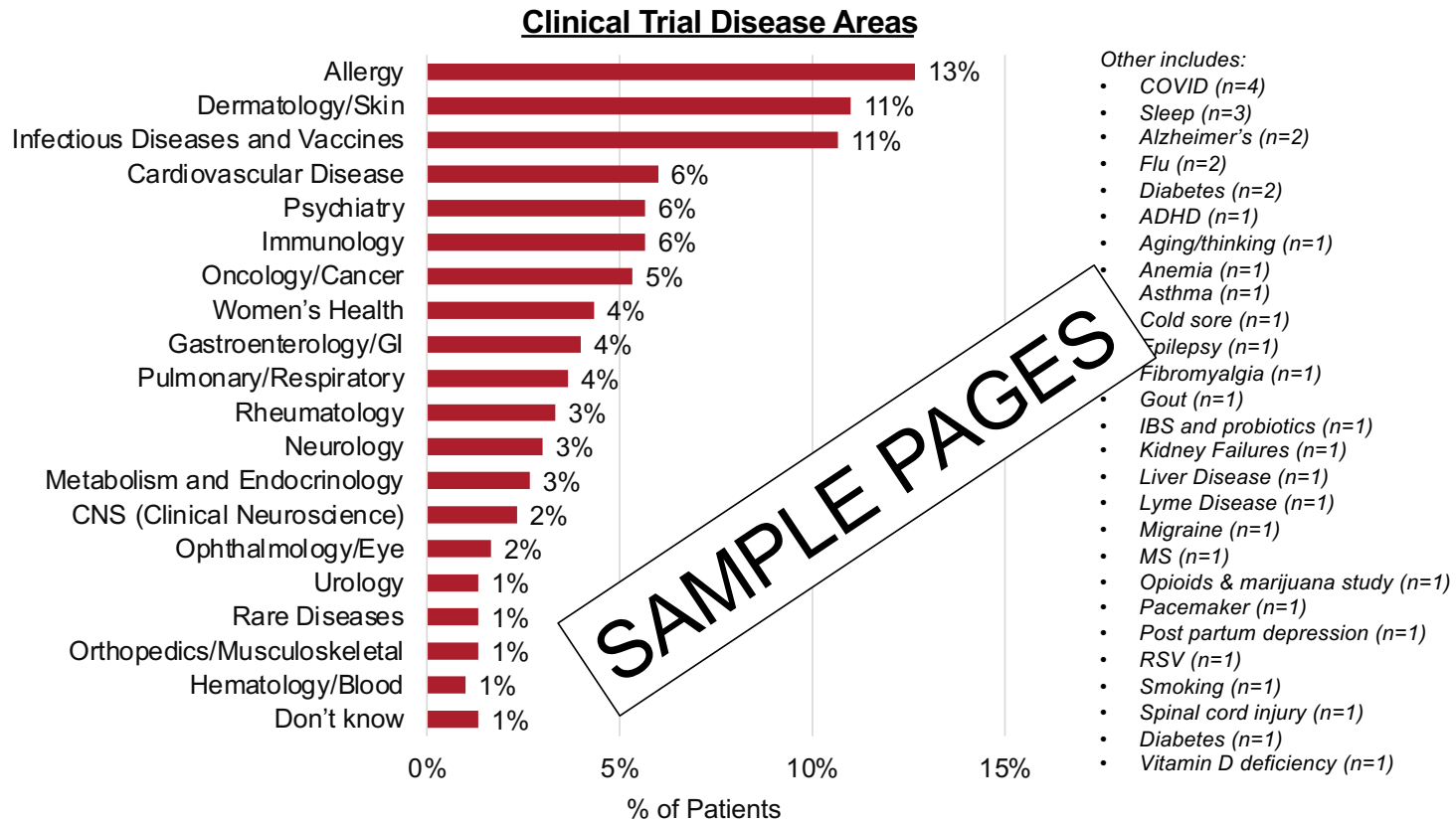
Other: Non-binary (n=2), Gender fluid (n=1), Genderqueer (n=1).

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- S1. Where are you located?
- S2. What best describes where you live?
- S3. How old are you?
- S4. With which gender do you identify?
- S5. What is your ethnicity?
- S6. What is your total household income?

# Patient Demographics

- All patients have participated in 1 or 2 clinical trials for a new therapy in development over the past 2 years.
  - Those who participated in more than 2 trials were excluded to avoid "routine" participants.



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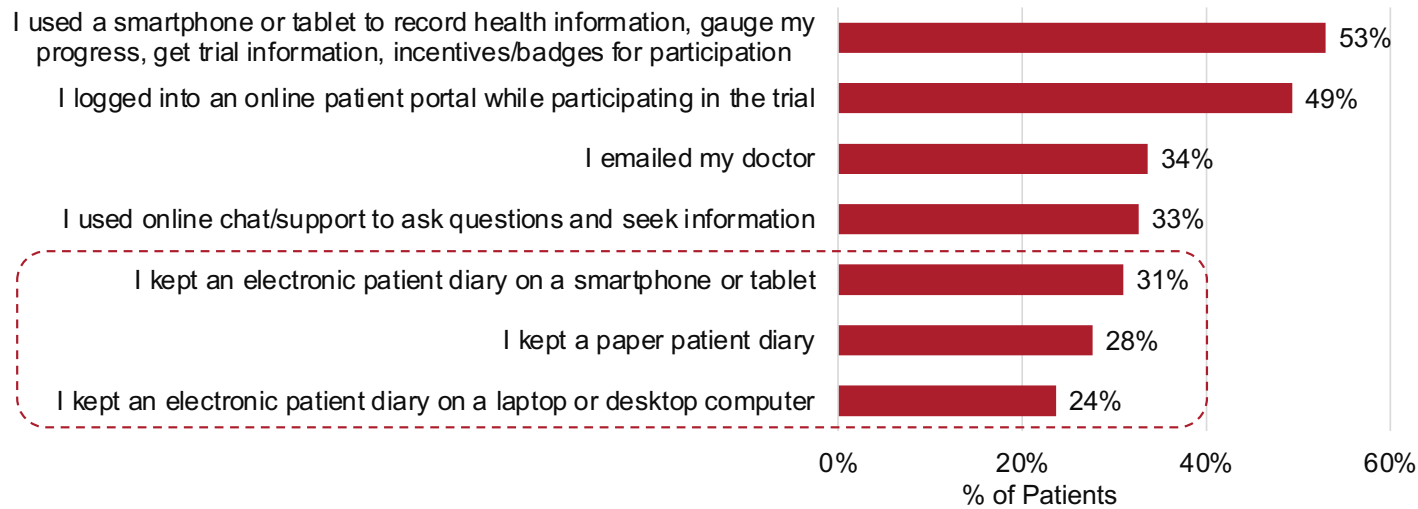
N=300

S7. Which of the following activities have you participated in during the past 2 years?  
 S8. How many clinical trials have you participated in over the past 2 years?  
 S9. What was the condition or disease area of the current or most recent clinical trial you participated in?  
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# Patient Demographics

## Activities Performed/Included in Clinical Trials



## Hours/Week Spent on Electronics Prior to Trial Participation



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N=300

S10. Which of the following elements or activities did you perform or were included as part of your clinical trial?

S11. Prior to your participation in the most recent clinical trial, how many hours per week did you spend on a smartphone, tablet, laptop, and/or desktop computer combined?

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## VI. About Life Science Strategy Group, LLC

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## About Life Science Strategy Group, LLC

**Life Science Strategy Group, LLC (LSSG)** is a life science consultancy specializing in strategic consulting and market research engagements across a variety of service, therapeutic and technology markets. Our core leadership team brings more than 30 years of combined experience conducting strategic consulting engagements in the following areas:

- Pharmaceutical
- Biotechnology
- Contract Research
- Contract Drug Manufacturing
- Diagnostics
- Drug Discovery

LSSG brings extensive breadth and depth of life science knowledge combined with seasoned consultants specializing in the biopharmaceutical services industry market research and strategy. They provide actionable and insightful strategic consulting results backed by data-driven market research.

***“Solid, responsive, and dependable. That’s why we work with LSSG.”***  
*VP Business Intelligence, Global Top-5 CRO*

For more information on the Life Science Strategy Group’s consulting and market research services, please contact [info@lifesciencestrategy.com](mailto:info@lifesciencestrategy.com).

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