Optional Add-On to a Feature Considered Essential

eConsent- You can do it!

MedStar Health

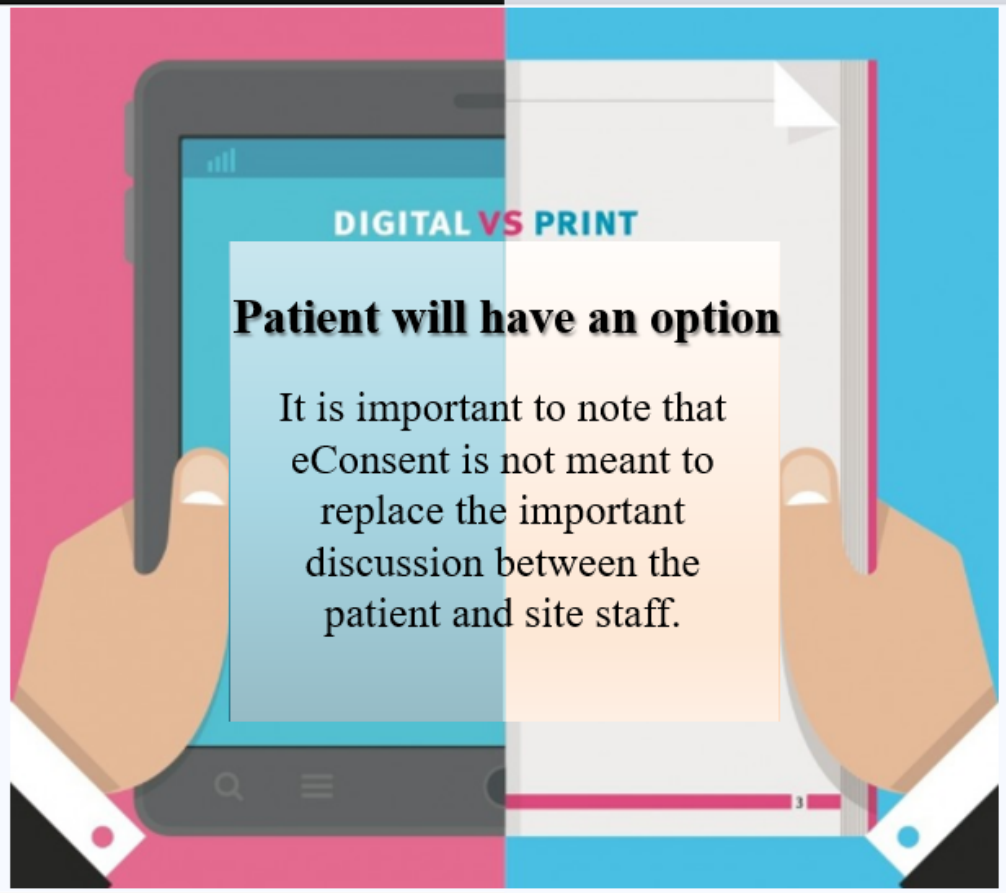
eConsent

Progress in eConsent solutions was slow, with the clinical research industry overdue to implement quick, secure, and flexible consent options. Most consent platforms were not 21 CFR compliant.

Then the COVID-19 public health crisis arrived and quickly became a major catalyst for eConsent adoption. The COVID-19 pandemic accelerated the rollout of eConsent.

eConsent

Electronic informed consent (eConsent) provides the same information, but in an electronic format.



As with traditional consenting, the site will continue to own the consenting process.

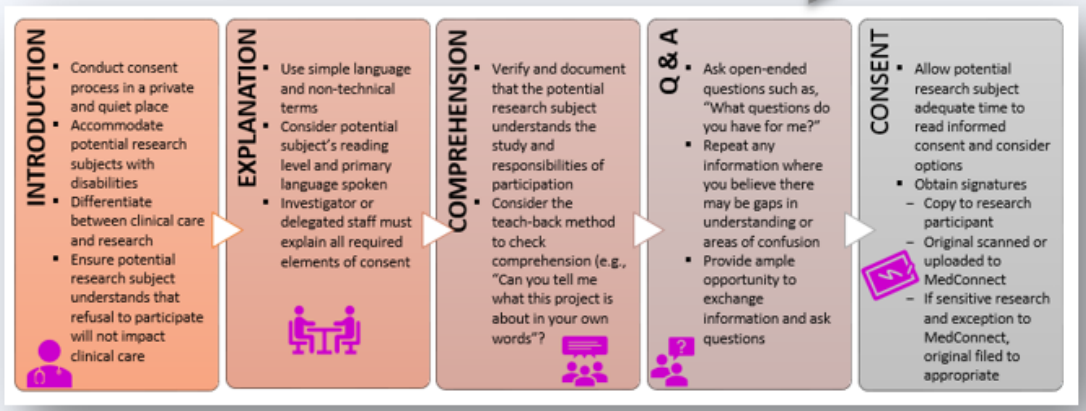
eConsent

No matter the format for the informed consent process
—paper or eConsent—
the responsibilities set forth in the regulations related to the
IRB and investigator have not changed.

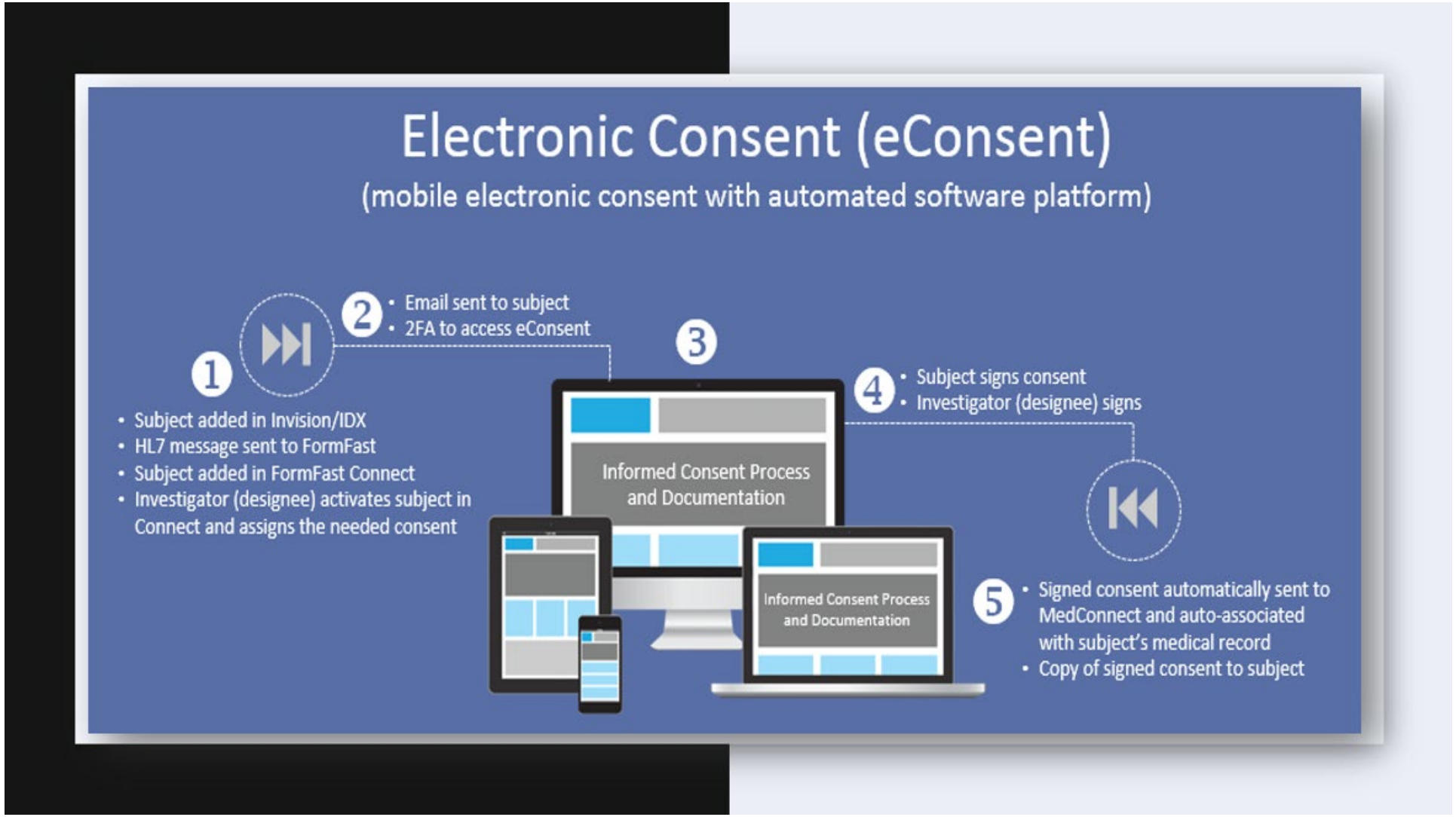
- Subject Recruitment
- Initial Telephone Screen

continues throughout

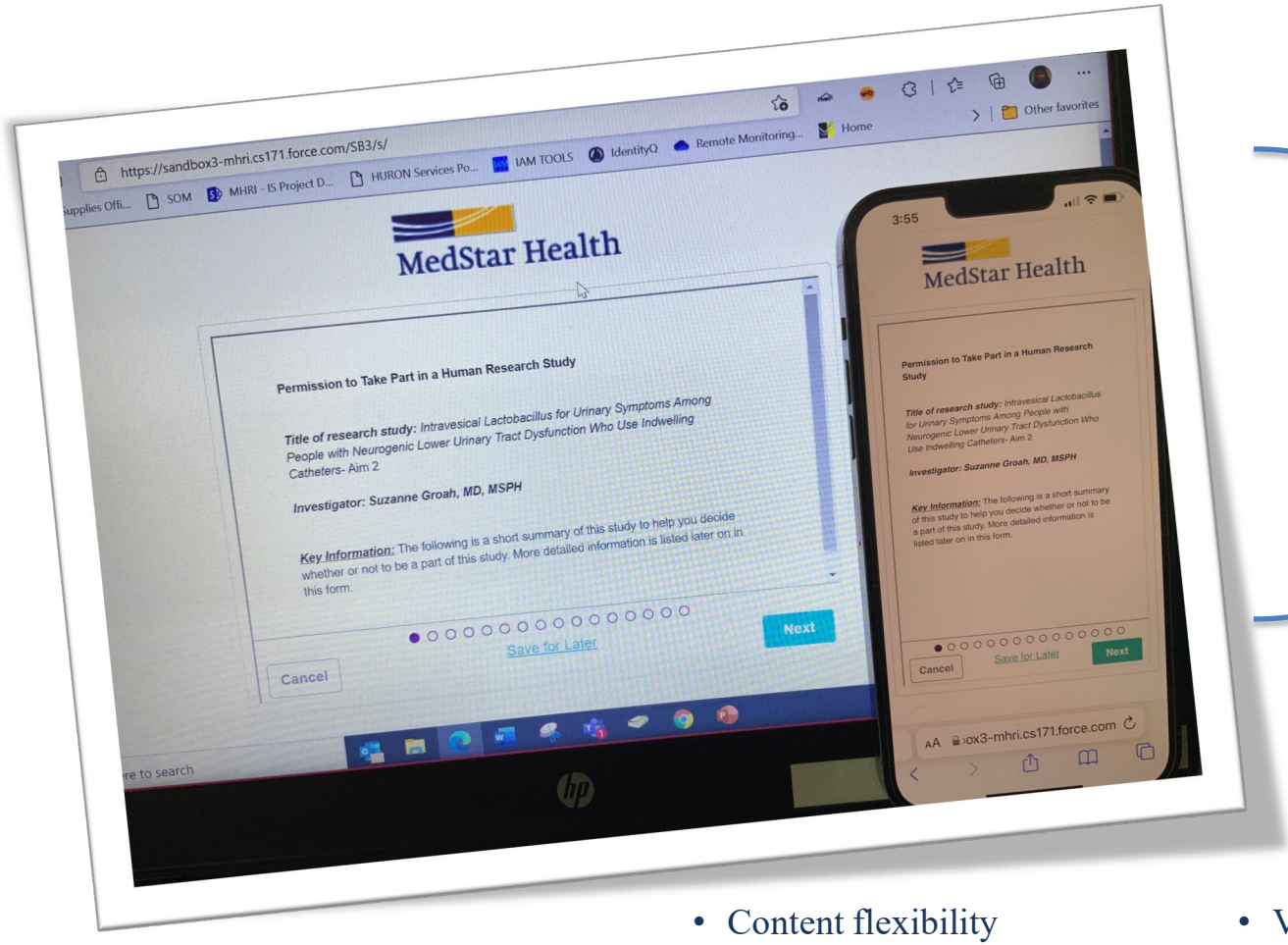
- Through conclusion of study



eConsent Workflow



Benefits and Features of eConsent



eConsent solution is fully compatible with any screen size and any device (e.g., phone, tablet, computer) and any browser (e.g., Apple Safari, Google Chrome, Microsoft Edge, Internet Explorer)

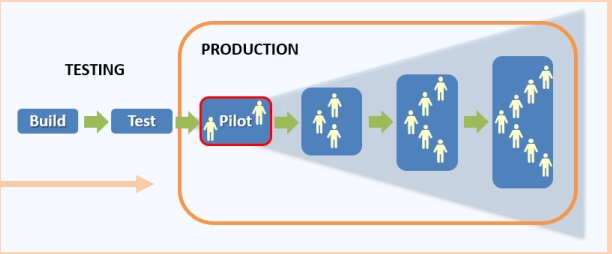
- Content flexibility
- Role-based access
- Meets regulatory requirements
- Embedded educational links
- Version management
- Audit trails
- Dashboard status
- 21 CFR compliant

MedStar Health

eConsent Roadmap

JANUARY 2022

- MHRI yearly mandatory research operations policy/procedure refresher training and introduced new eConsent procedure; training conducted on January 11 and January 13 with make-up training session on February 1
- Phased roll-out of new eConsent platform



2018

MHRI GUMC evaluation of eReg and eConsent systems

2019

2020

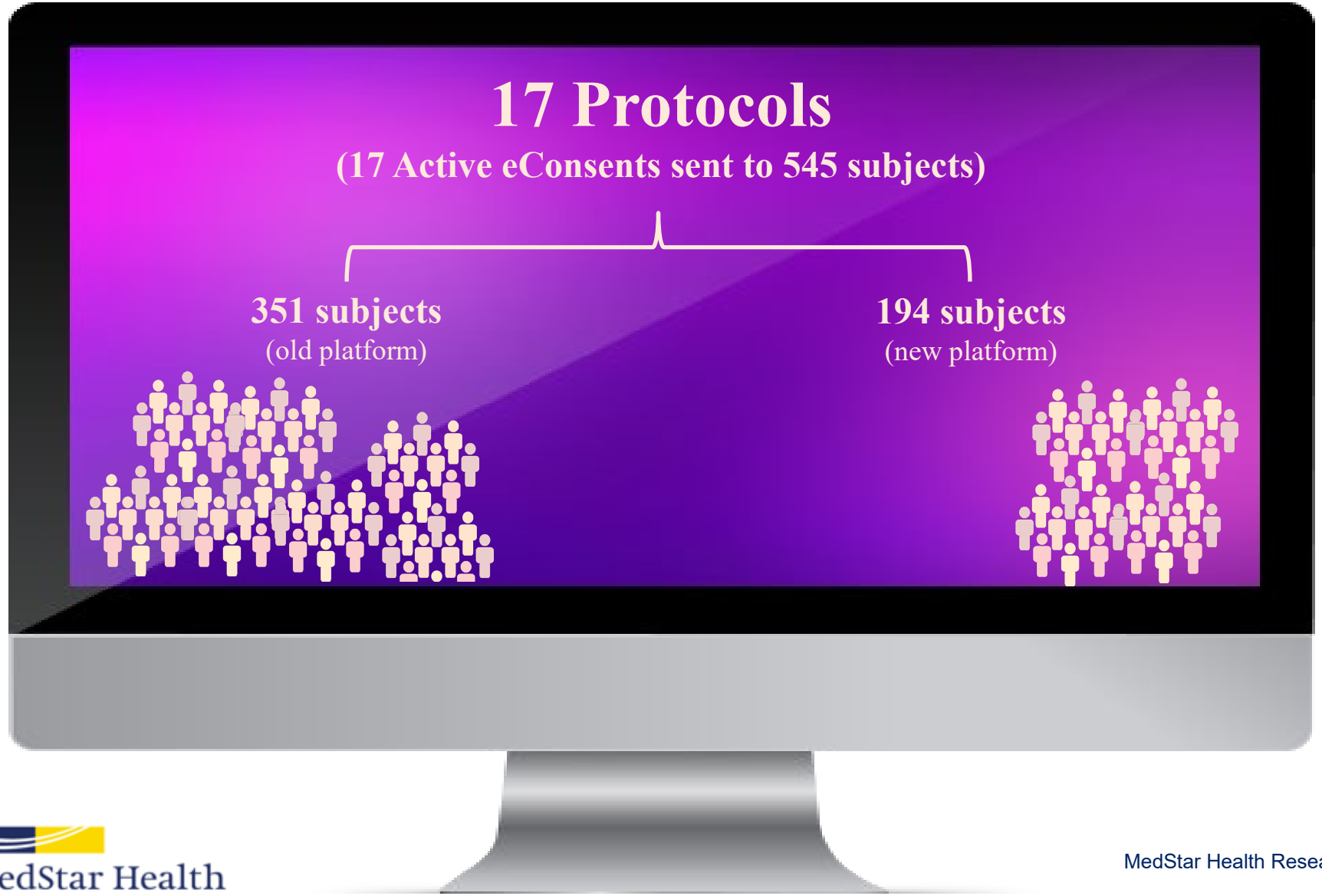
MHRI pilot (soft launch) of Interlace Health eConsent

2021

Rebuild and soft launch eConsent

2022

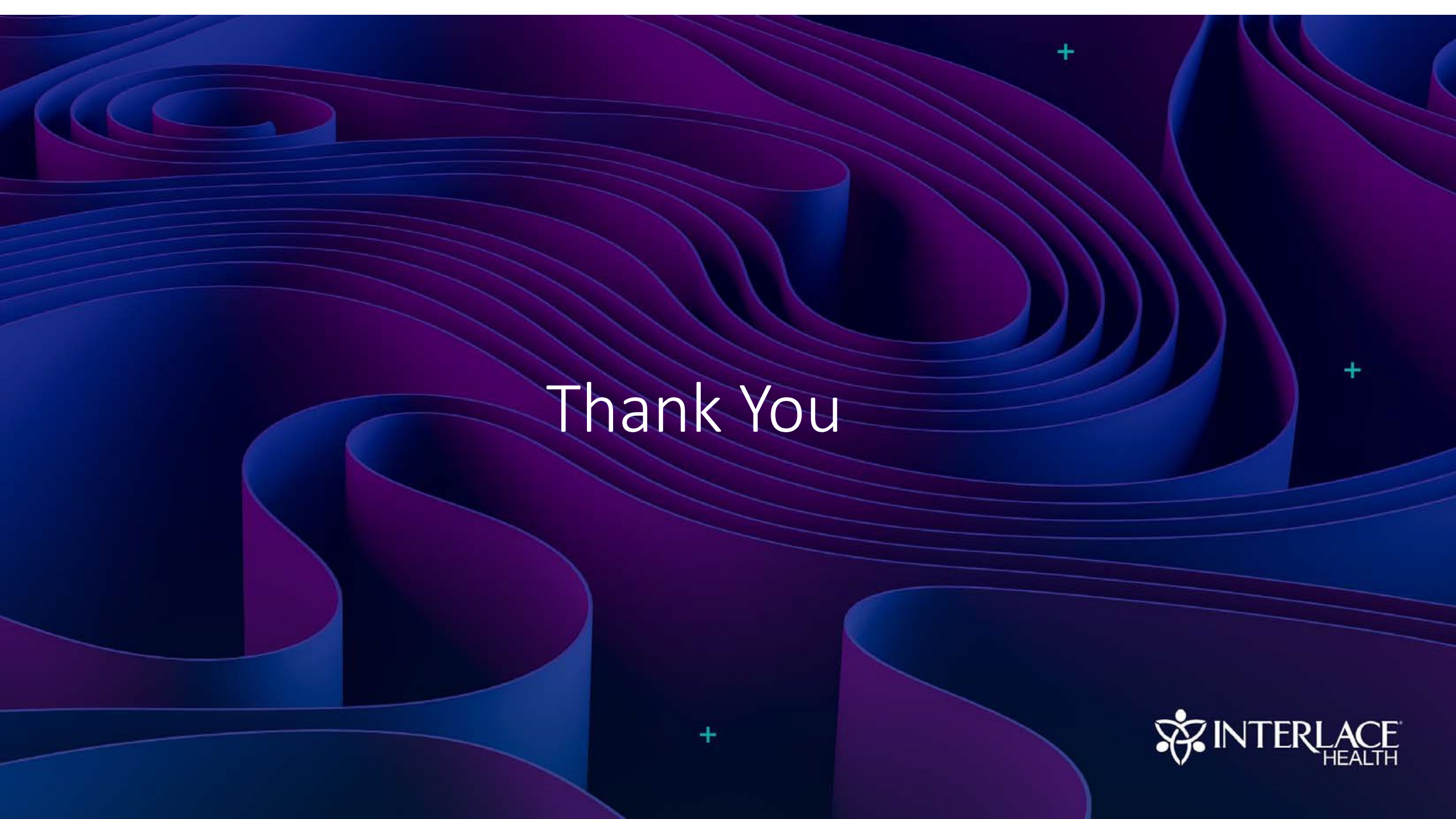
Active eConsents



eConsent the New Standard?

The eConsent model can be a flexible, user-friendly, and secure solution to informed consent when built and used appropriately.

Long after social distancing ends, remote eConsent functionality will no doubt continue to address the growing adoption of decentralized and hybrid trial designs.


Thank You
INTERLACE HEALTH