Impact of COVID -19 Crisis for Clinical Trials

- **Continuing Clinical Trials – Ethical discussion**
- **Continuity and Contingency Plan – Example of what we are doing now**
- **Ensuring Stability & Infrastructure for sites – Today and Tomorrow**

Continuing Clinical Trials – Ethical discussion

FDA Guidance…Covid-19

Local and State Orders / Regulations

Continue ongoing trials and subjects

- FDA Guidance clearly allows discretion to continue ongoing subjects and does not prohibit continuing enrollment of new subjects.
- We have an ethical obligation to participants, and to the integrity of the trial.

Enrollment of new subjects (many, but not all studies)

- Often, the only health care option of many subjects / patients
- Implement specific procedures for maximizing the safety of subjects
- Implement specific procedures for maximizing the safety of clinical research personnel

Preservation of Clinical Research Personnel / Sites – "minimize risk to trial integrity" (FDA Guidance)

- A prolonged delay (>2-4 weeks) of enrollment will have severe adverse consequences on continuity of research personnel and the overall quality of research operations
- Relieve burden to other health care settings (some evidence of increase subject participation), Mental Health service closures.

Continuity and Contingency Plan – Example of what we are doing now

Robust implementation – Pre-Office Visit Screening

- Volunteers are contacted prior to coming into office
- Drivers / transportation controls

Participant Distancing – Outpatient and Inpatient

- Volunteer distancing prior to entering clinic
- Volunteers *"Participant Distancing Rooms".*
- Face to Face prep first via "On-Site Video Communications"
- Clinical assessments required are conducted by sponsor approved & trained clinicians as usual. Solution, *"Participant Distancing Rooms" and* "On-Site Video communications"

Safety, Secure, Study data, collected by expert sites

- Inpatient studies we can provide 100% observation and 100% control over volunteer distancing.
- Staff are issued a badge with their credentials and name of company we are essential business and is proof of site staff member's necessity to travel to work.
- We want to get the message across , we can help with the collaboration as site with pharma

Ensuring the Stability & Infrastructure of Sites - Today and Tomorrow

Feedback from Sponsors on Current Situation and Future Impact

- Difficult decisions
- Confusion around next steps
- Economic instability impacts all stakeholders at some level
- ***Clinical research sites are "critical" to the Eco-System!***

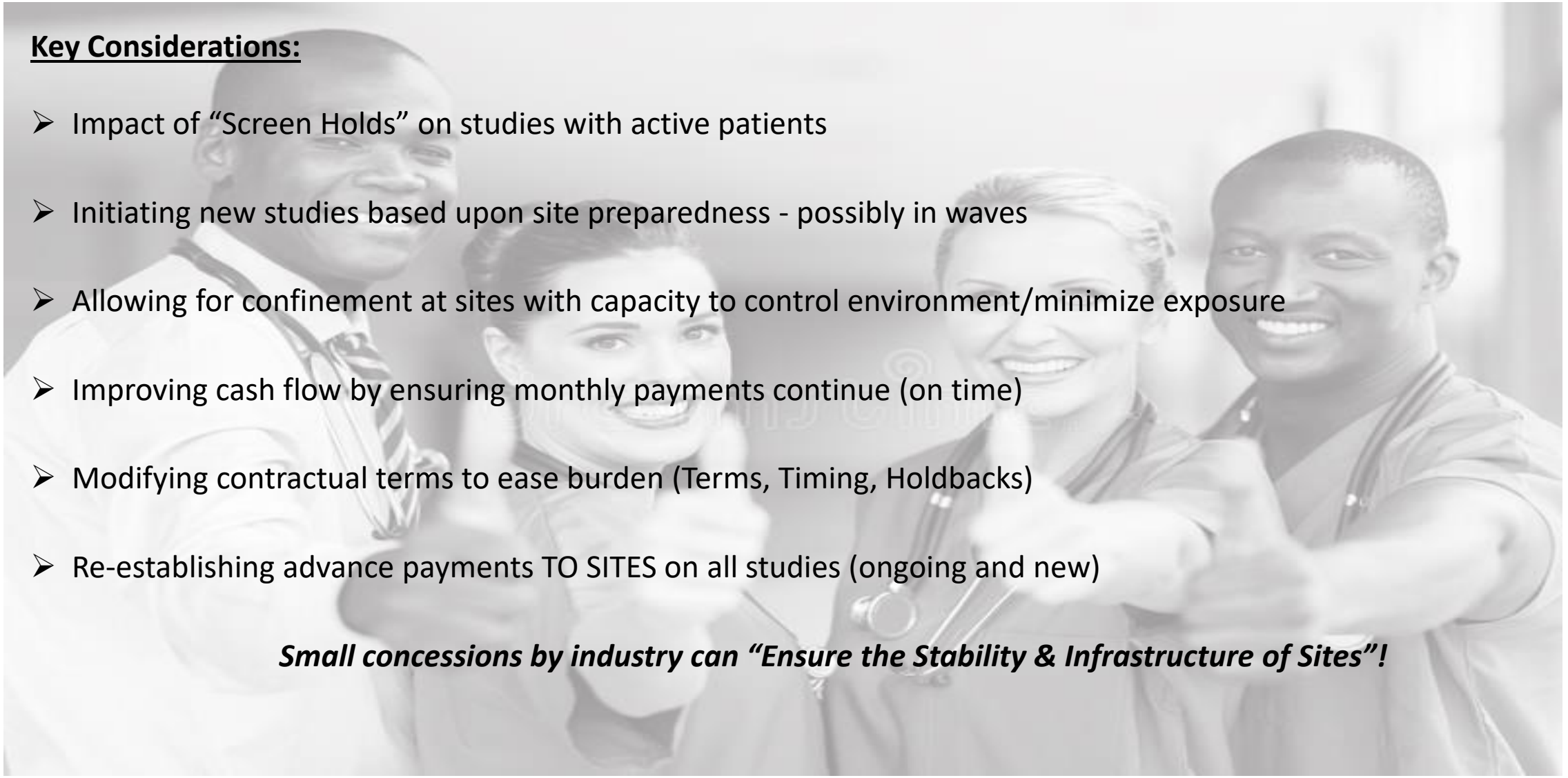
Financial Impact of Sponsor Decisions

- Industry panic
- Increases site costs
- Screening halted & new study delays = new revenue shutdown leading to potential cash crisis in ~30-60 days
- Remote monitoring & confines of existing contractual obligations
- Overhead is overhead . . . . Your study hold doesn't effect sites' monthly bottom line

Increase Costs associated with site modifications & accommodations are real and include:

- Short-Term: Staff childcare, PPE, Increased Transportation, etc.
- Long-Term: IT infrastructure accommodations

Ensuring the Stability & Infrastructure of Sites - Today and Tomorrow



Key Considerations:

- Impact of “Screen Holds” on studies with active patients
- Initiating new studies based upon site preparedness - possibly in waves
- Allowing for confinement at sites with capacity to control environment/minimize exposure
- Improving cash flow by ensuring monthly payments continue (on time)
- Modifying contractual terms to ease burden (Terms, Timing, Holdbacks)
- Re-establishing advance payments TO SITES on all studies (ongoing and new)

Small concessions by industry can “Ensure the Stability & Infrastructure of Sites”!

Contributors

Andria Chastain, Evolution Research Group
Elan Cohen, PhD, Hassman Research Institute
Larry Ereshefsky, Pharm.D, Hassman Research Institute
Howard Hassman, DO, Hassman Research Institute
Debra Hoffmeyer, CITrials
Kevin Quinn, CenExel Clinical Research
Bonnie Segal, Segal Trials
John G. Sonnenberg, PhD, Uptown Research Institute
Bobbie Theodore, Clinical Trial Centers Alliance
David Walling, Ph.D., CNS Trials
Tom Wardle, CenExel Clinical Research
Woody Woodaman, Synergy Research Centers
Lori Wright, Evolution Research

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