

LOCUS BIOSCIENCES

How a strong Sponsor / Clinical Site collaboration
can improve clinical trial performance

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Presentation Highlights

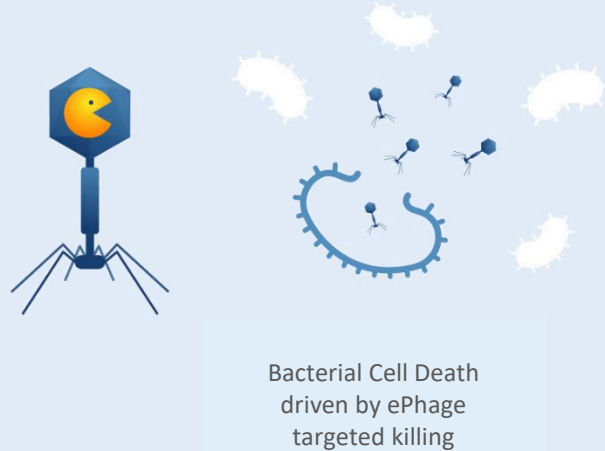
- The role of the clinical site during the planning phase.
- How a sponsor's study can stand out at a clinical site.
- Site vs patient centricity: how patient care can be impacted by a lack of foresight.
- How CROs and Sponsors can work with clinical sites to improve the quality of a trial.

Locus Biosciences, a North Carolina company from discovery to development



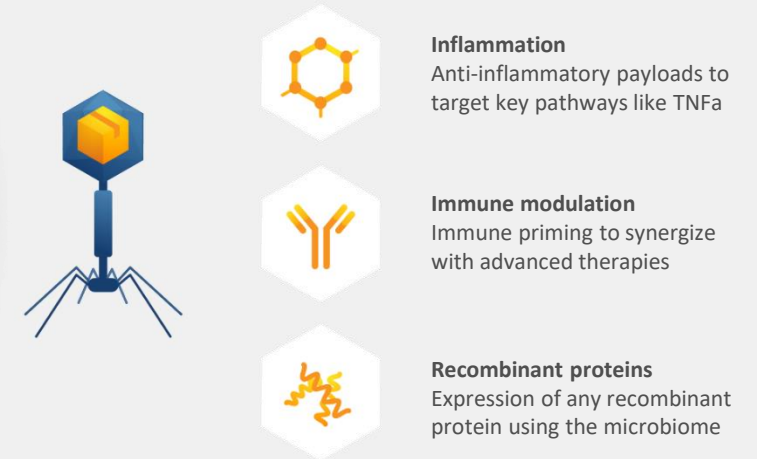
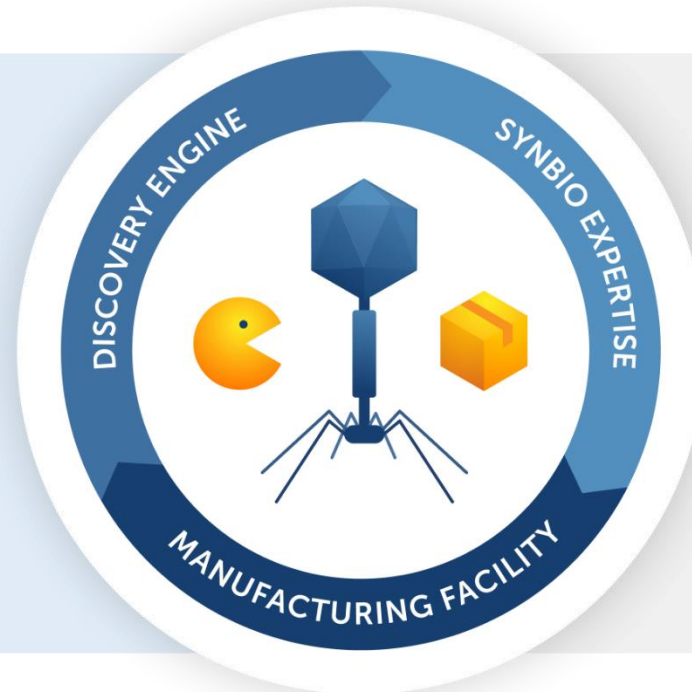
Locus's recombinant bacteriophage technology leverages the safety and precision of bacteriophage to deliver therapeutic payloads to target bacteria

Targeted Pathogen Removal




- Bacterial Infections (e.g., UTI)
- Immunologic Diseases with Bacterial Influence (e.g., IBD)
- Cancers with Bacterial Influence (e.g., CRC)
- Neurologic Diseases with Bacterial Influence (e.g., ASD)

Phage-delivered Biotherapeutics



- Immunologic Diseases with Inflammatory Influence (e.g., IBD)
- Cancers with Immunologic/Inflammatory Influence (e.g., CRC)
- Neurologic Diseases with Inflammatory Influence (e.g., ASD)

Locus product pipeline is strongly supported by multiple strategic partners, with partnerships advancing into new research modalities & therapeutic areas

PROGRAM	DISCOVERY	IND-ENABLING	CLINICAL	MARKETED	PARTNER	COMMERCIAL RIGHTS
Infectious Disease Pipeline						
Urinary Tract Infections – <i>E. coli</i>	<div><div></div><div></div><div></div><div></div></div>				<div> CARB-X</div>	Wholly-owned
Urinary Tract Infections – <i>K. pneumoniae</i>	<div><div></div><div></div><div></div><div></div></div>					Wholly-owned
Respiratory & Bloodstream Infections – <i>P. aeruginosa</i>	<div><div></div><div></div><div></div><div></div></div>					Wholly-owned
Respiratory & Bloodstream Infections – <i>S. aureus</i>	<div><div></div><div></div><div></div><div></div></div>					Wholly-owned
Microbiome Pipeline						
Inflammatory Bowel Disease	<div><div></div><div></div><div></div><div></div></div>					Wholly-owned

Experiences drive perspective



“Customers are the lifeblood of any company.”

“Everybody says, “the customer is king’ and “we work for the customer” and the “customer is the real boss.” But very few employees...do anything to demonstrate they believe in this dictum.”

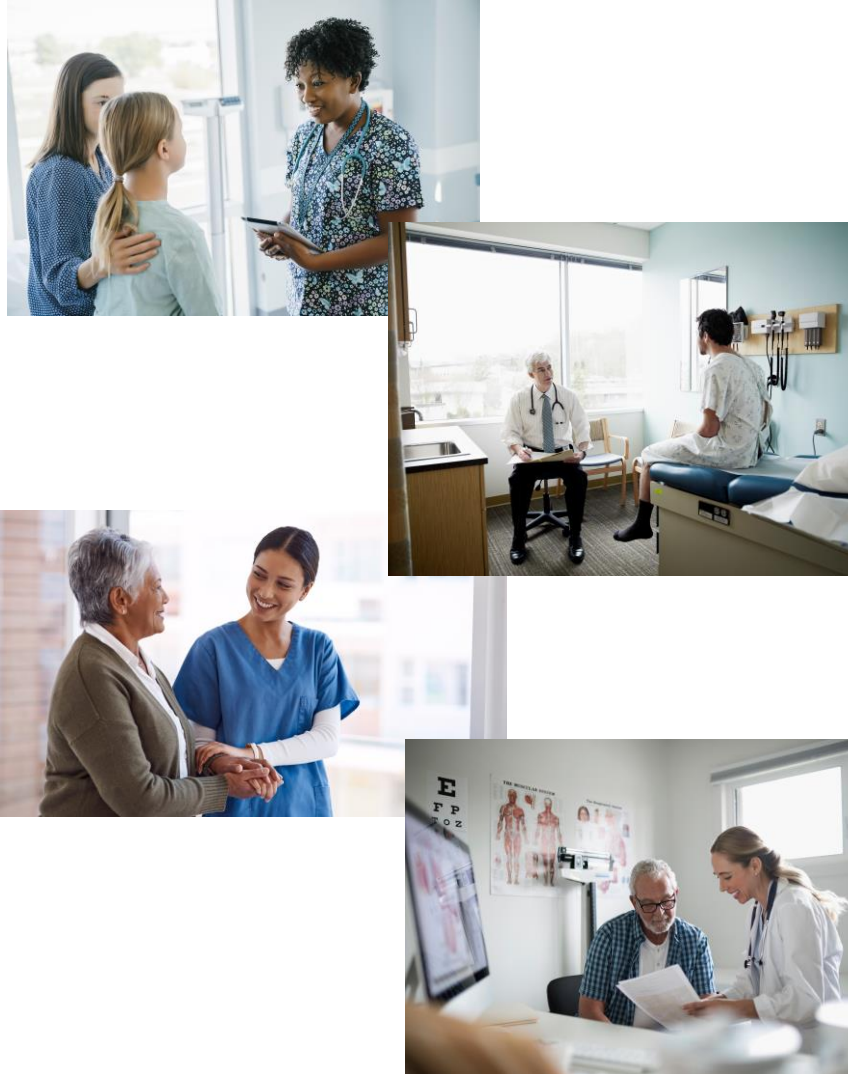
“They provide the ideas for new products and new applications. They provide the early warning signals about your products’ quality and timeliness. They know about your competitors. To know your customer is to know your future.”

“When the phone rings twelve people ought to dive to answer it.”

Jeffrey J. Fox, “How to Become a CEO: The Rules for Rising to the Top of Any Organization, 1998

Who are the key partners for Clinical Development success?

Patients



Clinical Sites

Inserting “patient” or “clinical site” for “customer”

“Patients are the lifeblood of clinical development.”

“Everybody says, “the patient is king’ and “we work for the patient” and the “patient is the real boss.” but very few employees...do anything to demonstrate they believe in this dictum.”

“Patients provide the ideas for new products and new applications. They provide the early warning signals about your products’ quality and timeliness. They know about your competitors. To know your patient is to know your future.”

“When the phone rings twelve people ought to dive to answer it.”

Likewise,

“Clinical Sites are the lifeblood of clinical development.”

“Everybody says, “the clinical site is king’ and “we work for the clinical site” and the “clinical site is the real boss.” but very few employees...do anything to demonstrate they believe in this dictum.”

“Clinical sites provide the ideas for new products and new applications. They provide the early warning signals about your products’ quality and timeliness. They know about your competitors. To know your clinical site is to know your future.”

“When the phone rings twelve people ought to dive to answer it.”

Focus on patient centrality much greater than site centrality

Microsoft Bing search results for "patient centrality in clinical trials". The search bar shows the query and filters. The results are categorized by "ALL", "WORK", "IMAGES", "VIDEOS", "MAPS", "NEWS", "CHAT", and "MORE". The "IMAGES" tab is selected, showing a grid of 16 image results. Each result includes a thumbnail, a title, and a checkmark indicating relevance.

Search results for "patient centrality in clinical trials":

- Clinical Drug Trials
- Decentralized Clinical Trials
- Clinical Study
- Clinical Trial Monitoring
- Clinical Trial Process Flow
- Clinical Trial Site
- Clinical Trial Types
- Patient Centrality
- Clinical Research Trials
- Medical Trials
- Clinical Trial Timeline

Image results include:

- How to Achieve Patient Centrality in Clinical Trials
- Enhancing Patient Centrality & Advancing Innovation in Clinical Research with Virtual Randomized Clinical Trials
- How Patient Centrality is Changing Clinical Trials
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Microsoft Bing search results for "site centrality in clinical trials". The search bar shows the query and filters. The results are categorized by "ALL", "WORK", "IMAGES", "VIDEOS", "MAPS", "NEWS", "CHAT", and "MORE". The "IMAGES" tab is selected, showing a grid of 16 image results. Each result includes a thumbnail, a title, and a checkmark indicating relevance.

Search results for "site centrality in clinical trials":

- Clinical Trial Data
- Clinical Trial Patient
- Clinical Trial Team
- Oncology Clinical Trials
- Clinical Trial Monitoring
- Clinical Trial Monitor
- Clinical Trial Study
- Human Clinical Trials
- Clinical Research Trials
- Medical Trials
- Cancer Clinical Trials

Image results include:

- Where Do We Begin in Terms of Patient Centrality?
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A site centric focus is necessary for a successful patient outcome

1

Protocol Design

A patient centric protocol won't be successful if it is unwieldy or burdensome for the clinical site to implement. Ensure the design works for patients and clinical sites!

2

Procedures

Procedures that are confusing or outside the normal practice lead to unintentional mistakes. Clinical sites hate making mistakes!

3

Technology & Equipment

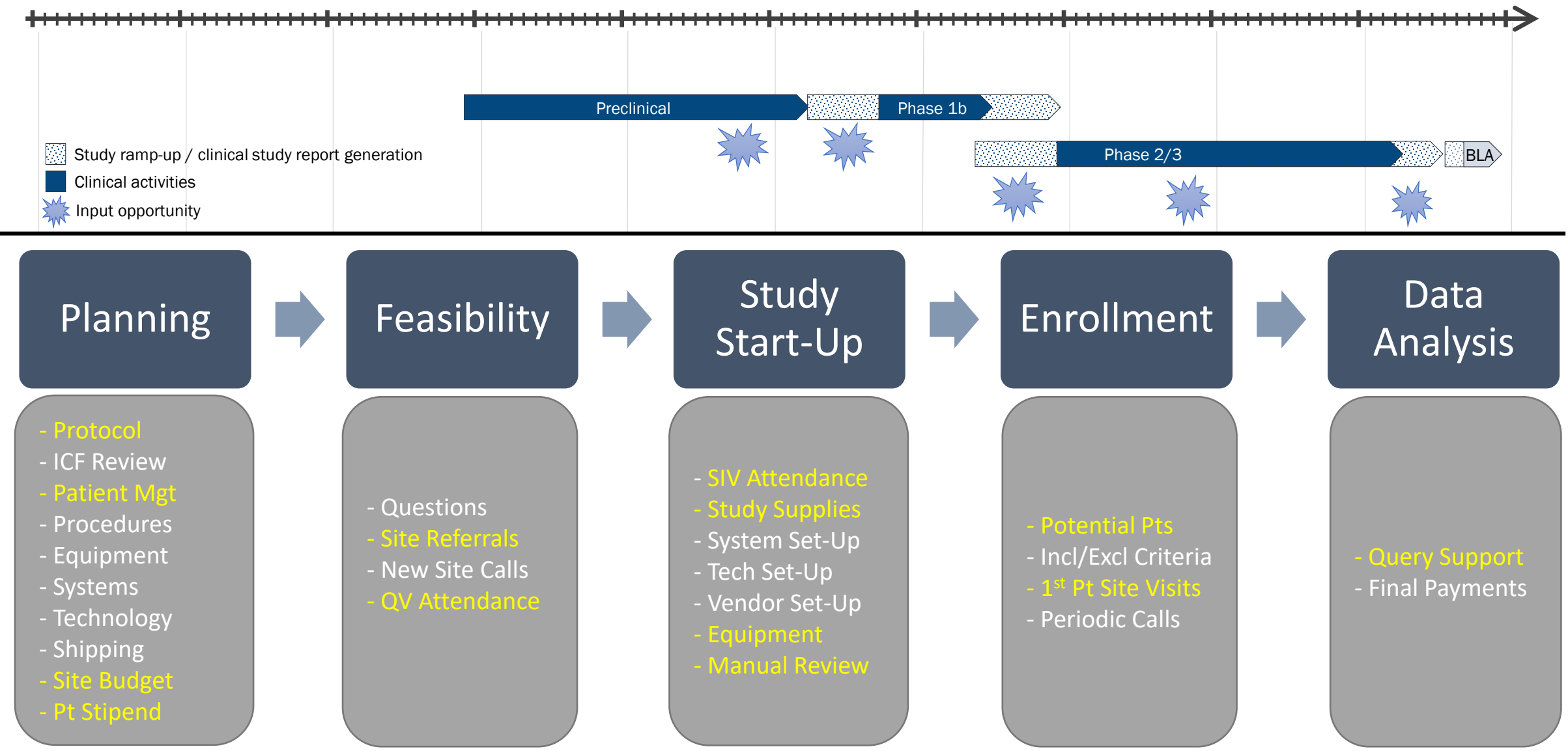
Consider technology carefully to ensure it meets the needs of patients, but also meets the needs of the clinical staff. Being on the “cutting edge” doesn't always drive success in your trial!

4

Clinical Site Budget

A well-structured budget will ensure that your clinical site is fairly compensated, and that patient stipends and reimbursements reflect their practice. An improper budget will fail to meet recruitment needs!

Opportunities exist for site centric activities throughout the clinical trial lifecycle



Challenges and opportunities of implementing a site centric program

Challenges

- It takes time and effort! I already have a lot on my plate
- “I think...” or “I believe...” is an information gap.
- Site visits are expensive.
- We already get patient input, isn't that enough?

Opportunities

- Set aside dedicated time each week for site calls. Give the study coordinator your direct line for quick calls or texts to build connections.
- Close the gap through site visits where you can observe and gather information about what is happening.
- Feedback to your bosses so they can see the value of the information collected. Invite them to travel to key sites with you. The connections and results are invaluable!
- That's half the equation – go the extra step to have the full picture. That's what will set you apart.

One Last Thing....



Call and visit your study coordinators often!

- Don't rely on others to do it or a technology gimmick

Listen to and observe their needs!

- Work together to determine how you can address those needs to ensure success.

Take action based on what you see and hear!

- It will set you apart from other Sponsors!



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