A PHASE 2b, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE SAFETY AND EFFICACY OF *STAPHYLOCOCCUS AUREUS* 4-ANTIGEN VACCINE (SA4Ag) IN ADULTS UNDERGOING ELECTIVE OPEN POSTERIOR SPINAL FUSION PROCEDURES WITH MULTILEVEL INSTRUMENTATION (Study B3451002)

Vaccine Research
A Pfizer Research Unit

Primary Objective

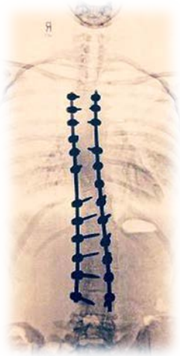
To assess the efficacy of SA4Ag in the prevention of postoperative ***S. aureus*** **blood stream infection (BSI) and/or deep incisional or organ/space surgical-site infection (SSI)** within 90 days of elective open posterior spinal fusion procedures with multilevel instrumentation, in adults aged 18 to <86 years.

Study Design

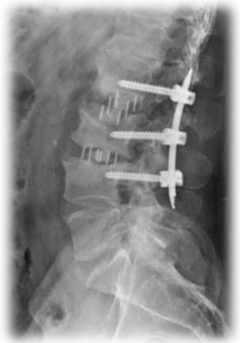
- 6000 patients expected to accumulate **48 per-protocol 'cases'** within 90 days of index surgery
- Multicenter, double-blind, randomized, placebo-controlled
- Subject participation 6 to 8 months
- Evaluations: efficacy, safety, tolerability, immunogenicity, SA colonization

Elective Open Posterior Spinal Fusion with Multilevel Instrumentation Procedure

'Spinal fusion' is defined as a surgical arthrodesis procedure



http://www.anatomybox.com/wp-content/uploads/2012/04/beforeandafter-spinalsx.jpg



http://www.ivanchengmd.com/patient-case-study-5.php

Multilevel instrumentation is defined as the surgical implantation of prosthetic material involving at least 3 vertebrae.

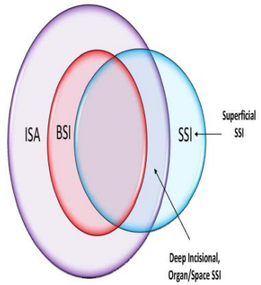
Scheduled Study Visits

	Visit 1	Visit 2			Visit 3	Visit 4	Visit 5	Visit 6
	Enrollment & Vaccination	Index Hospital Admission			Day 21 Phone Contact	Day 42 Post-op evaluation	Day 90 Post-op evaluation	Day 180 Post-op evaluation
		Day of Surgery	Day after Surgery	Day of Discharge				
Study Stage	VACCINATION STAGE	SURGERY STAGE						
Study Day	Day -60 to Day -10	Day 1	Day 2	Variable	Day 21	Day 42	Day 90	Day 180
Visit Window	Day -60 to Day -10	N/A	N/A	N/A	18 to 26	35 to 49	83 to 97	178 to 192

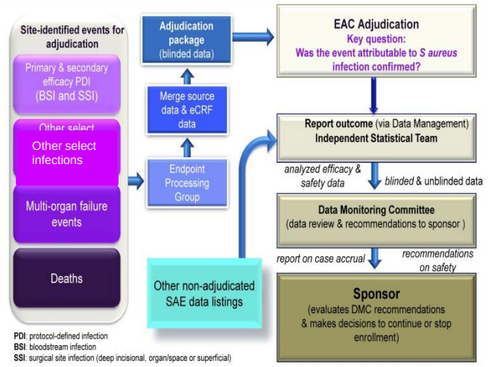
Protocol Defined Infections (PDI)

- PDI clinical criteria utilize NHSN surveillance criteria.

❖ Blood stream infections (BSI)
❖ Deep incisional SSI
❖ Organ/ Space SSI
❖ Superficial SSI
❖ Invasive *S. aureus* (ISA)



Efficacy and Safety Event Adjudication & Decision Flow Overview



Data Monitoring Committee

- DMC responsible for:
  - Assessing safety data throughout the study.
  - Assessing vaccine futility/efficacy against *S. aureus* disease at the interim analysis.
- Unblinded data will be provided by an Independent Statistical Team (IST) to enable the DMC to make assessments and recommendations.

Ideal sites

To meet recruitment target, ideal site must have:

- Access to potential subjects to meet recruitment goals (4-5 subjects/month).
  - Patients undergoing elective open posterior spinal fusion procedures with multilevel instrumentation.
- Study research personnel capable of:
  - Following patients daily during hospitalization.
  - Obtaining third party medical records.
  - Performing weekend visits if needed.
- Most sites are large academic institutions led by either neurosurgeon or orthopedic surgeon.

Patient Reminders

Recruitment Materials

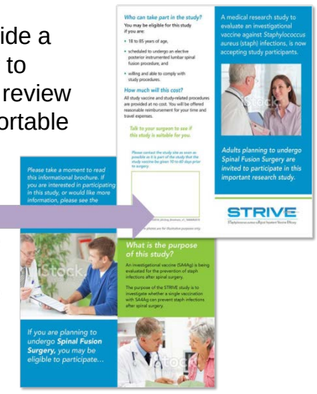
Posters & Contact Pads

• Posters provide a synopsis of the study and refer interested subjects .

• Contact pads are customized with site's contact information. They can be used as an attachment to the posters.

Recruitment Brochures

- Brochures provide a study summary to take home and review in a more comfortable setting.
- Brochures have a contact info area that can be customized with specific site and contact information.



Additional Recruitment Activities

• Recruitment assistants.
• App referral system.
• Website: strivestudy.com

STRIVE
STaphylococcus aureus suRgical Inpatient Vaccine Efficacy