

# Description of the Laboratory of Bacterial Polysaccharides

Willie F. Vann, Ph.D., Chief

Laboratory of Bacterial Polysaccharides

# Mission of the Laboratory of Bacterial Polysaccharides

- The Laboratory of Bacterial Polysaccharides investigates the biochemistry, biology and chemistry of virulence factors of encapsulated bacteria.
- These basic research fields are related to the regulatory activities of the Laboratory of Bacterial Polysaccharides.
  - Review and approval of BLA and IND submissions related to vaccines against encapsulated pathogens.
  - Evaluation of manufacturing and changes in the manufacturing
  - On-site inspections and technical meetings with manufacturers
- The Laboratory of Bacterial Polysaccharides also serves as a CBER resource for expertise in glycobiology as is exemplified by cross-cutting collaborations.
  - Example: glycosylation of viral vaccines

# Description of the Laboratory of Bacterial Polysaccharides

<b>Name</b>	<b>Position</b>	<b>Research Group</b>
Mustafa Akkoyunlu, MD, PhD	Senior Investigator	Cellular Immunology
Margaret Bash, MD	Medical Officer	Molecular Epidemiology
John Cipollo, PhD	Senior Investigator	Vaccine Structure
Daron Freedberg, PhD	Senior Investigator	Structural Biology
Willie F. Vann, PhD	Chief LBP, Senior Investigator	Glycobiology
Maria F. Haurat, PhD	New PI	Synthetic Biology

# Description of the Laboratory of Bacterial Polysaccharides

<b>Name</b>	<b>Research Group</b>	<b>Area of Research Covered</b>
Mustafa Akkoyunlu, MD, PhD	Cellular Immunology	Interaction of carbohydrate antigens with the immune system
Margaret Bash, MD	Molecular Epidemiology	Role of non-capsular antigens in protection
John Cipollo, PhD	Vaccine Structure	Role of glycoconjugates in host pathogen interactions
Daron Freedberg, PhD	Structural Biology	Structure and conformation of capsular polysaccharides
Willie F. Vann, PhD	Glycobiology	Biosynthesis of capsular polysaccharides

# Regulatory Activity

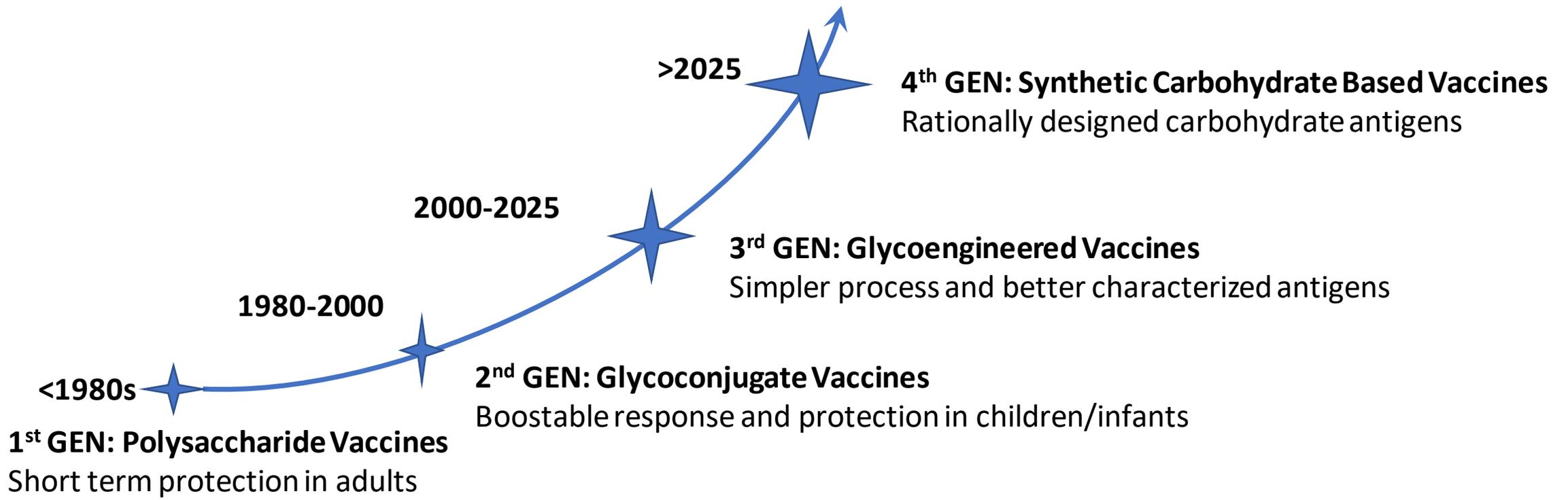
- Major Accomplishments- Requires many months review by multidisciplined team
  - **2018**- Licensure of **VAXELIS**-Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine
  - **2020**- Licensure of **Menquadfi**- Meningococcal (Groups A, C, Y, W) Conjugate Vaccine
  - **2021**- Review of 2 original biological license applications for licensure of new vaccines
- Some Other Accomplishments
  - Review of hundreds of IND submissions
  - Review and approval of 222 BLA supplements

# Perspective of Laboratory Organization

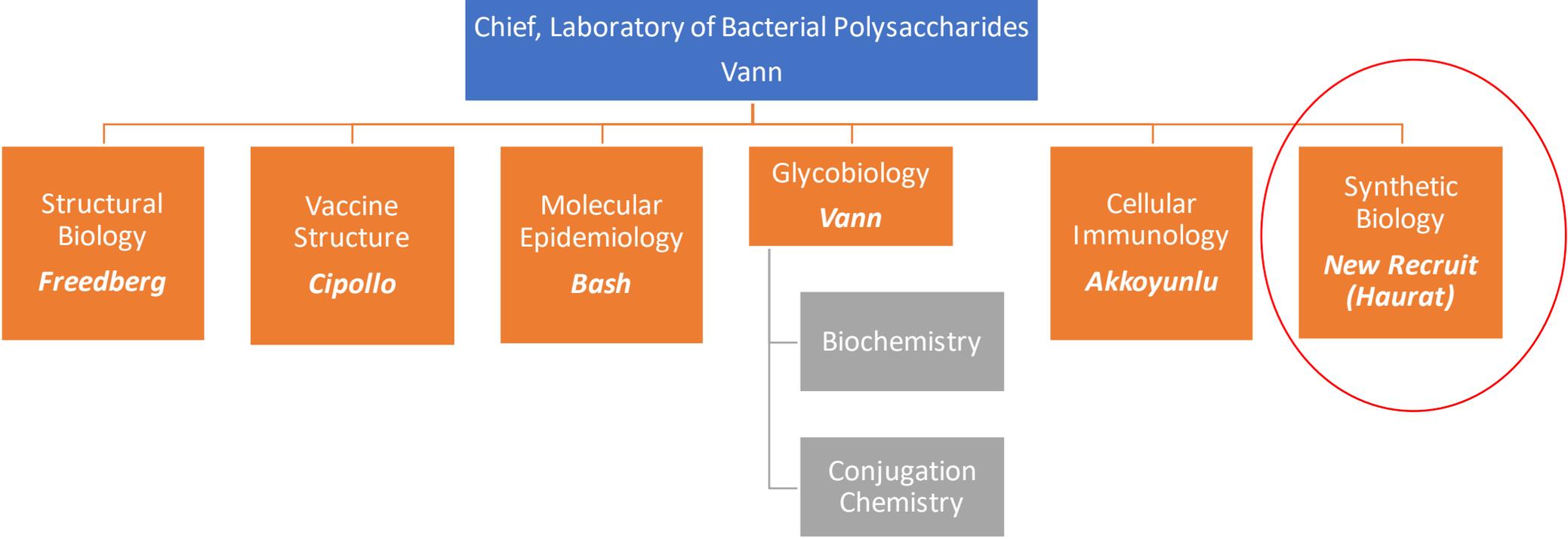
- The laboratory is organized to address existing issues related to vaccines against encapsulated pathogens and in anticipation of issues arising from the evolution and growth of glycoconjugate vaccines based on technological advances.



# Historical and Future Trajectory of Polysaccharide Based Vaccines



# ORGANIZATION OF THE LABORATORY OF BACTERIAL POLYSACCHARIDES



<b>Name</b>	<b>Research Group</b>	<b>Area of Research Covered</b>
Mustafa Akkoyunlu, MD, PhD	Cellular Immunology	Interaction of carbohydrate antigens with the immune system
Margaret Bash, MD	Molecular Epidemiology	Role of non-capsular antigens in protection
John Cipollo, PhD	Vaccine Structure	Role of glycoconjugates in host pathogen interactions
Daron Freedberg, PhD	Structural Biology	Structure and conformation of capsular polysaccharides
Willie F. Vann, PhD	Glycobiology	Biosynthesis of capsular polysaccharides
<b>Maria F. Haurat, PhD</b>	<b>Synthetic Biology</b>	<b>Metabolic engineering of glycoconjugates</b>

# Impact of COVID-19 on Progress of Research Programs in LBP

As with most of the scientific community, the SARS CoV 2 pandemic resulted in decreased research activities across FDA.

- **March 2020** all non-COVID related research projects in CBER were halted.
- **Two SARS CoV 2 projects allowed to operate at approximately 25% work capacity during this period** managed by Dr. Akkoyunlu and Dr. Cipollo
- **September 2020** Based on CBER policy, some of LBP staff resumed non-COVID related projects working 8-16 hrs/week on a voluntary basis.