



# Next-Generation Combination Products

## Emerging Innovations

### COMBINATION PRODUCTS SUMMIT

FT. WORTH, TX • NOVEMBER 28-30, 2023  
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## Moderator

**Susan Neadle,**

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## Speakers

**Dan Groszmann**

Director of Engineering, Amgen

**Geoff Hamilton**

Chief Executive Officer, Stemson Therapeutics

**Steven Oh**

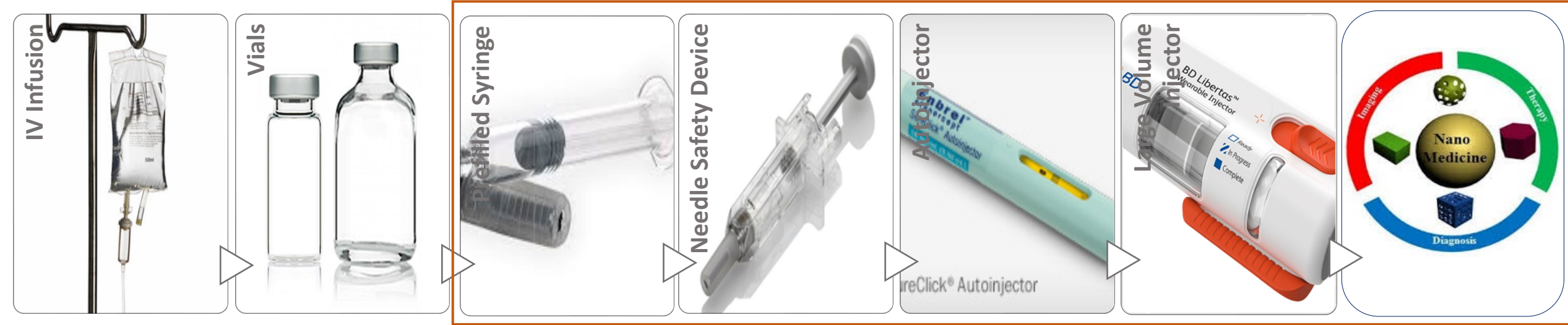
Deputy Office Director, Office of Cellular Therapy and Human Tissue, Center for  
Biologics Evaluation and Research (CBER), FDA

**James Wabby**

Global Head, Regulatory Affairs (CoE) – Emerging Technologies, Devices, and  
Combination Products & Volwiler Senior Research Industry Fellow – Regulatory  
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# Evolution of Drug Delivery



Ease of Use, Reduce Overfill

Patient safety, Regulatory

Adherence, competition, patient

Patent, Vol/Visc., Patient (IV-SC)

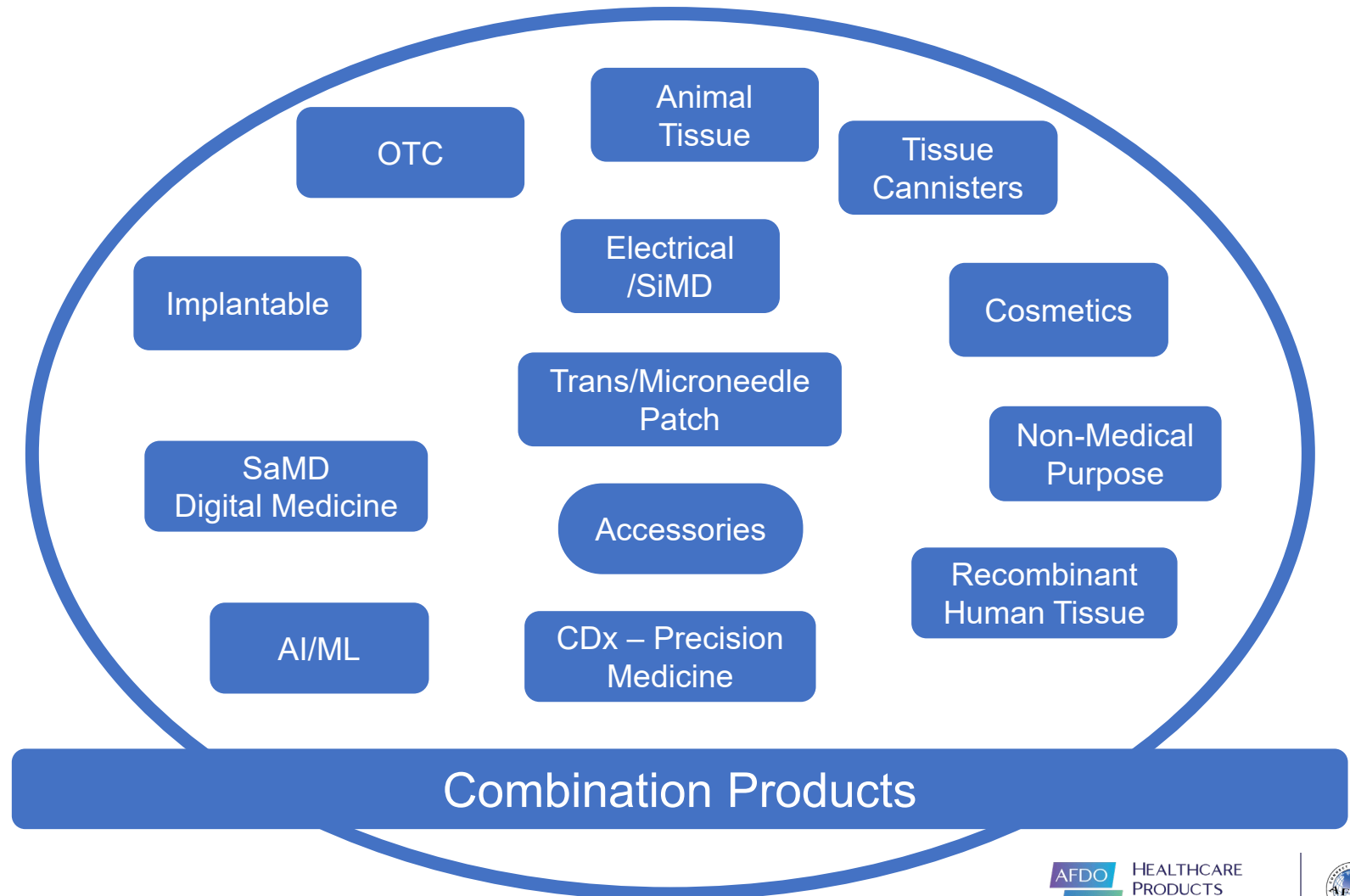
# Nanotherapeutics: Future Industry Portfolio

## Disruptive Medicine Innovation:

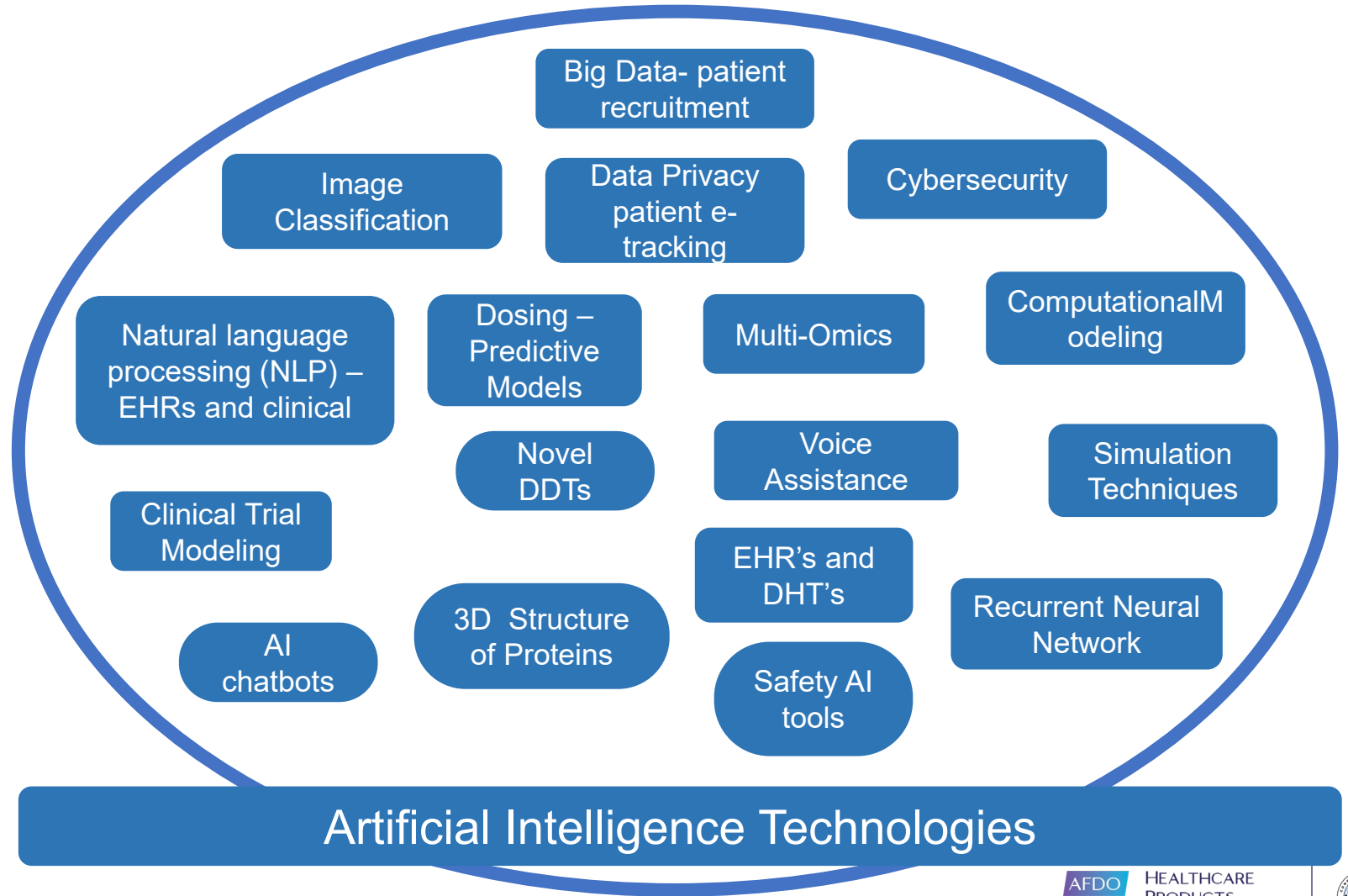
Combining precision diagnostics and precision therapeutic/aesthetic products for unmet medical needs and next generational needs - product lifecycle management.

## Future Product Strategy:

Being able to construct, fabricate, regulate, and apply therapeutic and/or aesthetic biopharma and devices with a size in the nano-range (at least one dimension) to support user focused products.



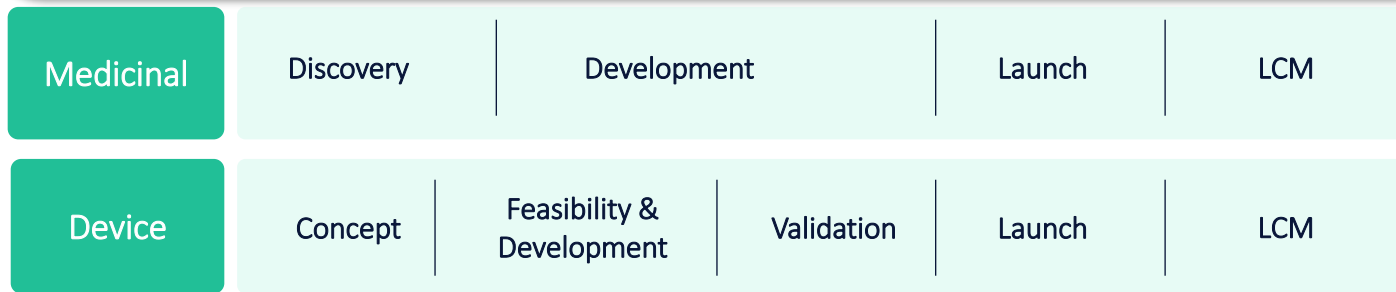
# New Tools and Concepts Utilization: Combination Product Development Clinical Trials






# Complex Product Development Overview



Device development integrated with medicinal development across the lifecycle...




 Currently pre-launch device development happens within 'Development' phase of medicinal development, but the vision is for it to start much sooner integrated with medicinal development

...for all device technologies in all Therapeutic Areas



 Example Device Technologies	 Example Therapeutic Areas	
<ul style="list-style-type: none"> <li>• Combination Products</li> <li>• Standalone Devices</li> <li>• Digital Health Tools (e.g., AI/ML)</li> <li>• Diagnostic Devices (e.g., CDx)</li> </ul>	<ul style="list-style-type: none"> <li>• Immunology</li> <li>• Oncology</li> <li>• Neuroscience</li> <li>• Ophthalmology</li> </ul>	<ul style="list-style-type: none"> <li>• Respiratory</li> <li>• Specialty Products</li> <li>• Cardiovascular</li> <li>• Virology</li> </ul>

## Regulatory Vision

- **Combination products:** Address high priority issues with combination products while evaluating future state strategies with an “enterprise mindset”
- **Major markets:** Evaluate strategies with a primary focus on core markets and other markets - document the strategy upfront.

# Emerging Innovative Products



The regulatory submission and approval process for emerging innovative products will continue to evolve.

Emerging Innovative Products will continue to evolve and grow:

- **Digital Medicine:** mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine
- **Molecular Diagnostics:** diagnostics based on linking symptoms of a disease to specific DNA/RNA, or other biomarkers
- **ATMPs: Advanced Therapy Medicinal Products** are cellular therapy products that include cellular immunotherapies and other types of autologous and allogenic cells for therapeutic indications. Human gene therapy refers to products that introduce genetic material into a person's DNA to replace faulty or missing genetic material



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## Panel Discussion

- Industry, FDA, and Participants

