

ClotChip™ by XaTek

AMP'D Arena

October 21 , 2019

John Zak MD, MBA – CEO & Co-founder



Today's Diagnostic Dilemma in Coagulation Care

- There are numerous clinical scenarios with no available diagnostic tool to provide clinically actionable data
- There is no universal point-of-care diagnostic available today to assess global hemostasis

The Solution to Personalized Coagulation Care

The XaTek ClotChip™ IVD assay can accurately provide clinically actionable data at the point-of-care for virtually any patient – regardless of the underlying cause of bleeding, thrombosis or surgical risk.

- a. drug-induced anti-coagulation therapies
 - i. Target Specific Oral Anti-Coagulants
 - ii. Anti-platelet
 - iii. Aspirin-based therapies
- b. congenital coagulopathies
- c. trauma-induced coagulopathies
- d. bleeding of unknown origin
- e. pre-surgical screening

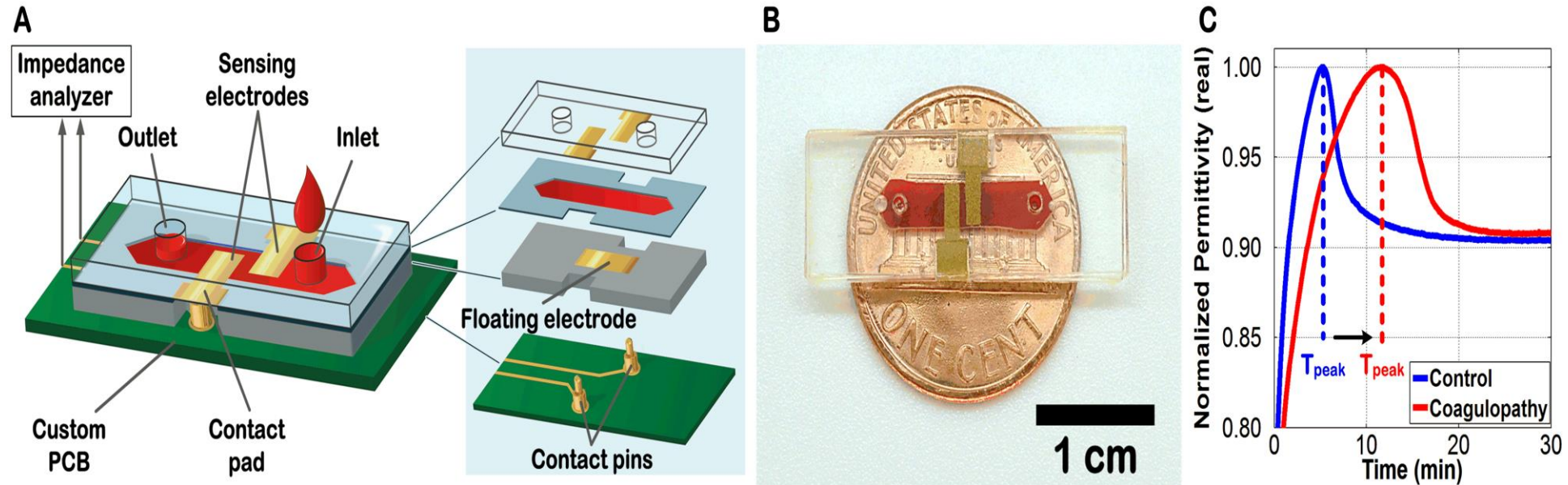
XaTek is currently under NDA with 5 global companies in the pharmaceutical and medical device industries

Features

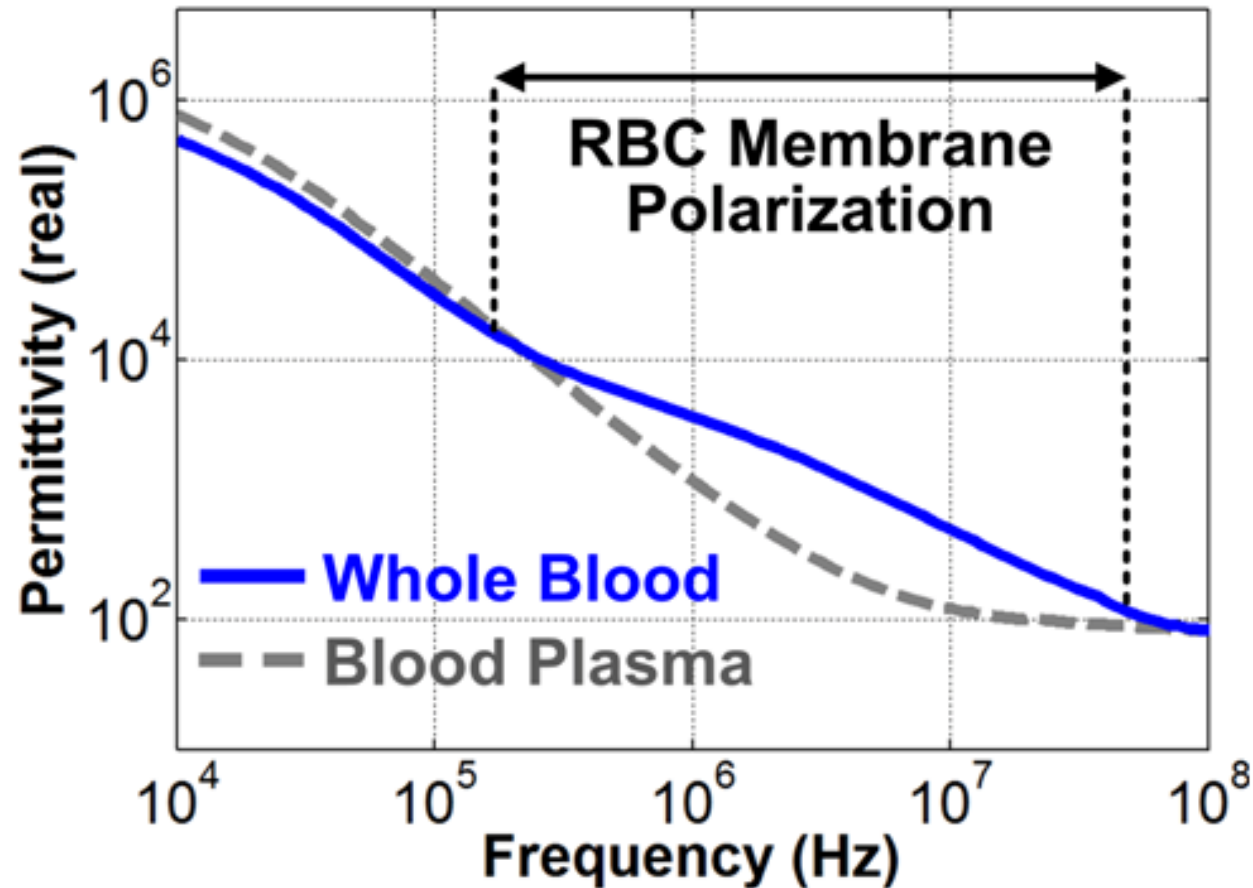
- Dielectric spectroscopy (DS) to monitor blood coagulation
 - Fully electrical technique
 - Single-use, disposable cartridge
 - Requires less than 10 μL of whole blood
- Sensitive to complete hemostatic process
- Discriminates b/w coagulation and platelet defects
- Assesses bleeding profile for any patient
- Provides opportunity for personalized coagulation care



ClotChip™ ClotChip™ 3D Sensor w/ Floating Electrode



- Parallel-plate capacitive sensing structure to extract dielectric permittivity of whole blood in a microfluidic channel
- Size = 26 mm × 9 mm × 3 mm
- Sample volume = 9 μ L



- Dielectric spectroscopy measurement with human whole blood and blood plasma in a microfluidic channel

ClotChip™ Data Points for Global Hemostasis

Results

- Exhibits high degree of sensitivity to anticoagulant effect of DOACs – *presented ASH 2016, 2018*
- Able to establish bleeding phenotypes for improved hemophilia care – *to be presented ASH 2019*
- Shows promising sensitivity to Emicizumab and Fitusiran – *presented ASH 2018*

Ongoing Research

- Capable of monitoring factor replacement therapy in Hemophilia – *feasibility trial TBC 2019*
- Correlates well with peak/trough levels of Xa inhibitors – *feasibility trial TBC 2019*
- Potential to displace PT/INR as a screening tool for general population – *feasibility trial TBC 2020*

Near-term Work

- Multicenter pivotal clinical studies w/ handheld device planned for Q2 2020 launch
 - Ability to predict pre-surgical bleeding risk in Xa inhibitors trial n = 400-600
 - Hemophilia trial n = 300-400
– *considering strategic partners*



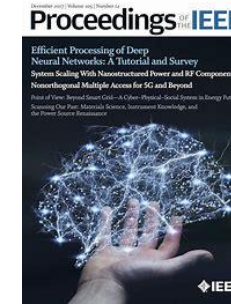
ClotChip™ Peer Reviewed Presentations at a National Conference



Presentation name	Conference	Presenter	Type	Date	Honors
A Miniaturized Microfluidic Dielectric Sensor for Point-of-Care Assessment of Blood Coagulation	ASH (San Diego, CA)	Evi Stavrou MD	Press Presentation (oral)	December 05, 2016	“Best in Conference”
A Miniaturized Microfluidic Dielectric Sensor for Point-of-Care Assessment of Blood Coagulation	ASH (San Diego, CA)	Evi Stavrou MD	Poster	December 06, 2016	
Assessment of a Novel Dielectric Microsensor for Monitoring Coagulation Factor Therapy in Children with Hemophilia with and without Inhibitors	ASH (Atlanta, GA)	Sanjay Ahuja MD	Poster	December 10, 2017	
A Novel Point-of-Care Therapy in Patients with Hemophilia	ASH (San Diego, CA)	Sanjay Ahuja MD	Poster	December 02, 2018	
Monitoring the Effects of Direct Oral Anticoagulants with a Novel Point-of-Care Sensor: Results of a Pilot Clinical Study	ASH (San Diego, CA)	Aman Opneja MD	Oral	December 03, 2018	“Best Abstract Submission”
Assessment of Bleeding Phenotype in Hemophilia A By a Novel Point-of-Care Global Assay	ASH (Orlando, FL)	Sanjay Ahuja MD	Poster	December 08, 2019	

ClotChip™ Publications

- **ClotChip: A Microfluidic Dielectric Sensor for Point-of-care assessment of Hemostasis.** Maji et al., *IEEE Transactions On Biomedical Circuits And Systems*, vol. 11, no 6, December 2017
- **Assessment of Whole Blood Coagulation with a Microfluidic Dielectric Sensor.** Maji et al., *Journal of Thrombosis and Haemostasis*, 16: 2050-2056, November 2018
- **A Novel Point-of-care, Whole-blood Assay Utilizing Dielectric Spectroscopy is Sensitive to Coagulation Factor replacement Therapy in Haemophilia A Patients.** Maji et al., *Haemophilia*. July 7, 2019



XaTek Commercialization Team

Management

- John Zak MD, MBA – President, CEO, co-founder
- Bill Stuart BS, MBA – Project Manager
- Kristen Chalet MBA – Comptroller
- 7 - member Board of Directors

Scientific

- Pedram Mohseni PhD – Co-inventor
- Michael Suster PhD – Co-inventor

Product Development

- Nottingham Spirk (Cleveland, OH)
- Sparton Medical (Cleveland, OH)
- Galen Data (Houston, TX)

Regulatory

- Medicept (Boston, MA)
- Navigant (Chicago, IL)

Quality

- Navigant (Chicago, IL)

Reimbursement

- Mirepoix (Boston, MA)

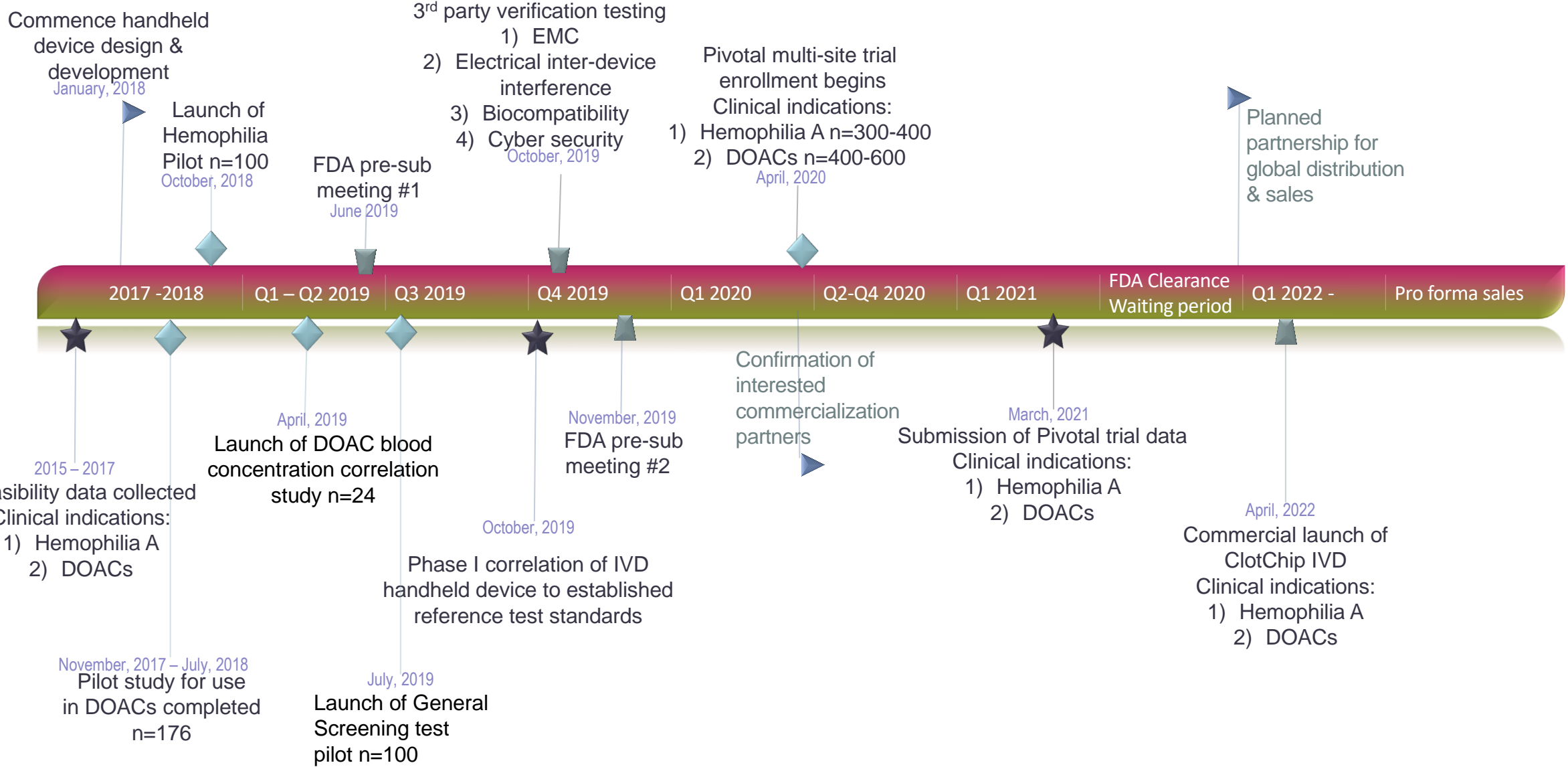
Intellectual Property

- Tarolli Sundheim Covell (Cleveland, OH)
- Rankin Hill & Clark (Cleveland, OH)

International Clinical Steering Committee

- Sanjay Ahuja MD – Case Western Reserve University/University Hosps of Cleveland (Cleveland, OH)
- John Alexander MD, MHS – Duke University (Raleigh-Durham, NC)
- Harry Buller MD, PhD – Academic Medicine Center in Amsterdam (Netherlands)
- James Douketis MD - McMaster University (Toronto, Ontario)
- Leslie Raffini MD – University of Pennsylvania/Children’s Hosp of Philadelphia (Philadelphia, PA)
- Gary Raskob PhD, MPH – University of Oklahoma (Oklahoma City, OK)
- Jeffrey Weitz MD – McMaster University (Toronto, Ontario)

ClotChip™ Development Plan Overview



XaTek Capitalization

- Founded in November 2016
- Seed-round in December 2016
- Series A round \$9,100,000 in May 2018
 - Over subscribed in <90 days
 - \$17,000,000 post money valuation
- Series B
 - Contemplated for Q1 2021
 - Raise/valuation TBD