VA TeleOncology and Decentralized Clinical Trials

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ChooseVA

SHOULDER to SHOULDER
Every Step of the Way

Agenda

01 Overview of VA Oncology and Precision Oncology Initiative

02 VA National TeleOncology Service

03 Decentralized Clinical Trials

04 Impact of COVID on Oncology Care

Who We Serve – Demographics

Compared to non-Veteran US Population, Veterans have slightly higher overall cancer rates

- **Sex**: In 2017, VHA looked across all facilities for the most common cancers of males and female Veterans.

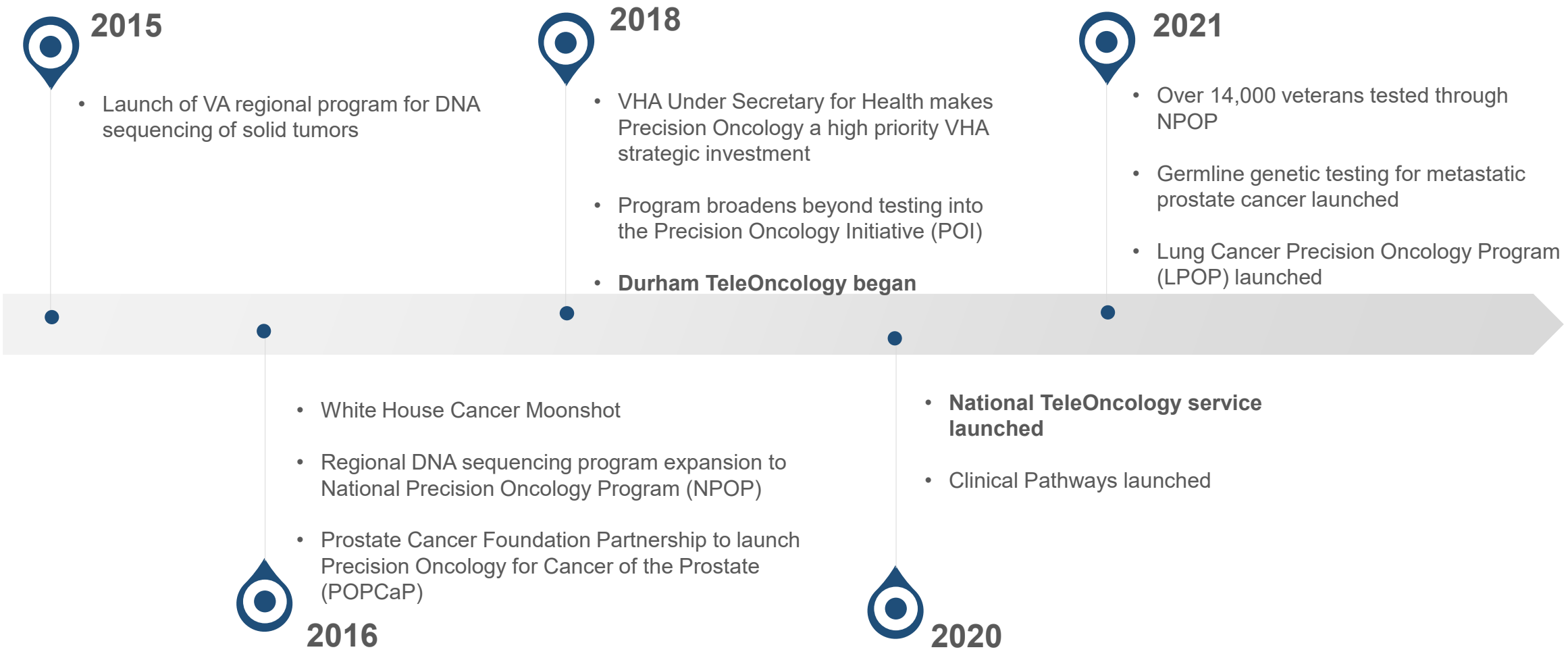
	n	%	**Males**	**Females**		n	%
Prostate	13,438	30%			Breast	402	30%
Lung & bronchus	8,019	18%			Lung & bronchus	197	15%
Colon & rectum	3,705	8%			Colon & rectum	88	7%
Kidney & pelvis	1,733	4%			Uterine corpus	75	6%
Melanoma	1,674	4%			Melanoma	59	4%
Liver	1,553	3%			Thyroid	53	4%
All Sites	**44,836**	**97%**			**All Sites**	**1,330**	**3%**

Prostate cancer in men and breast cancer in women are almost double that of the next most commonly occurring cancer.

- **Race**: An estimated 50,000 Veterans are diagnosed with cancer annually:
  - 79% were White; 19% were Black; 1% were Other Race
- **Residence**: Veterans are 2.5 times more likely to live in rural areas

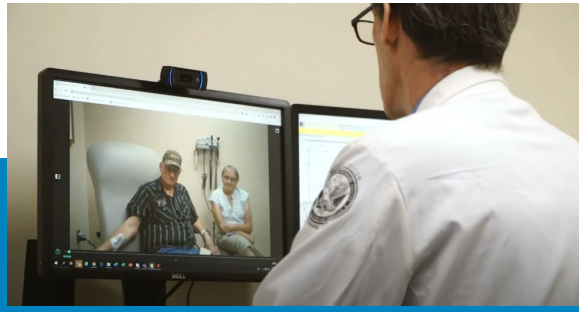
Data Sources: VA Cancer Care Registry (VACCR)

Evolution of VA Precision Oncology



VA National TeleOncology Service

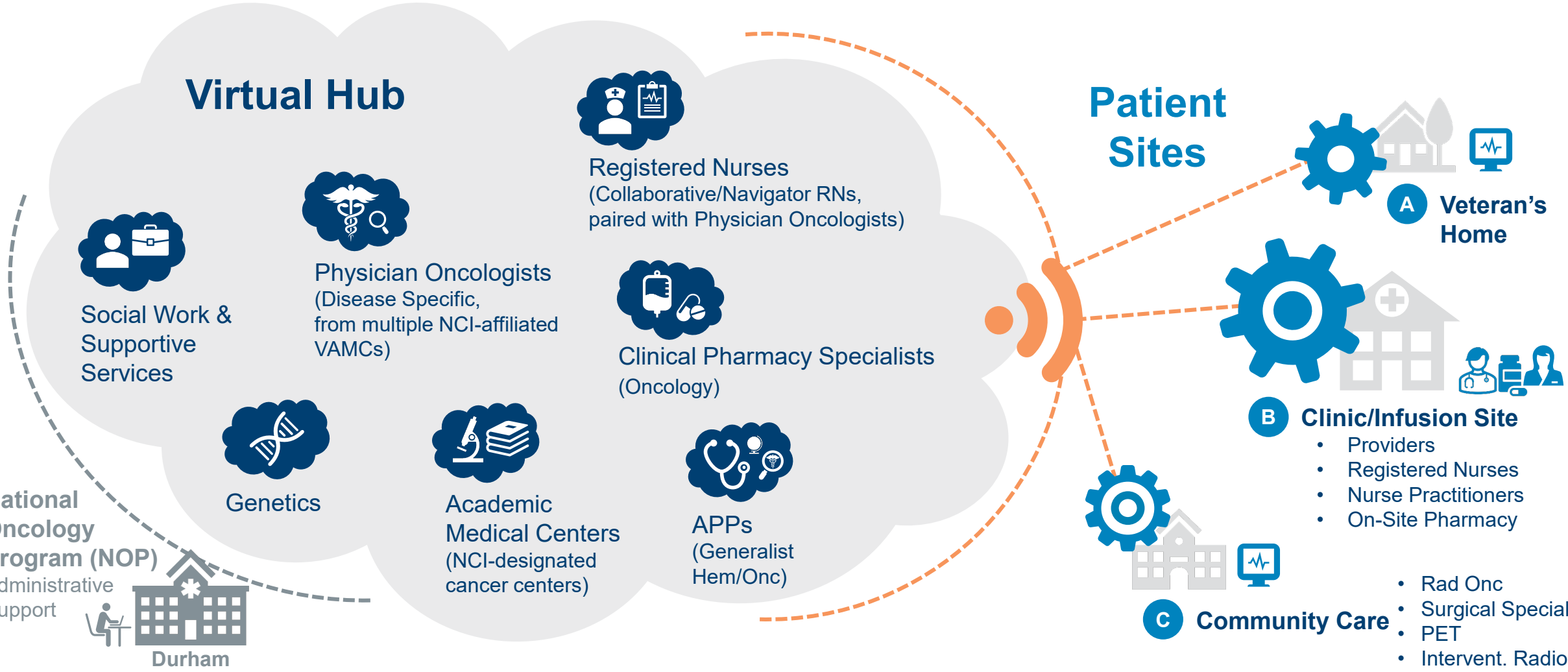
- Problem: misalignment of supply of (urban) and demand for (rural) oncologists
- Primary Goal: Improve access to care for Veterans with cancer, including timeliness of cancer care
- VA has well-developed telehealth resources, including national services for radiology, genetic counseling, and Tele-ICU
- Institute Virtual Cancer Center(s) similar to NCI-designated Comprehensive Cancer Center
  - Providers with specialization in patient's cancer type & involved in research
- Improve efficiency and precision of clinical practice
- Initial focus on Medical Oncology in context of multidisciplinary care
- Targeted service areas
  - Smaller VA medical centers
  - Larger VA medical clinics (health care centers)
  - Smaller VA medical clinics (community-based outpatient clinics)
  - Non-VA location, including Community partners and patient's home



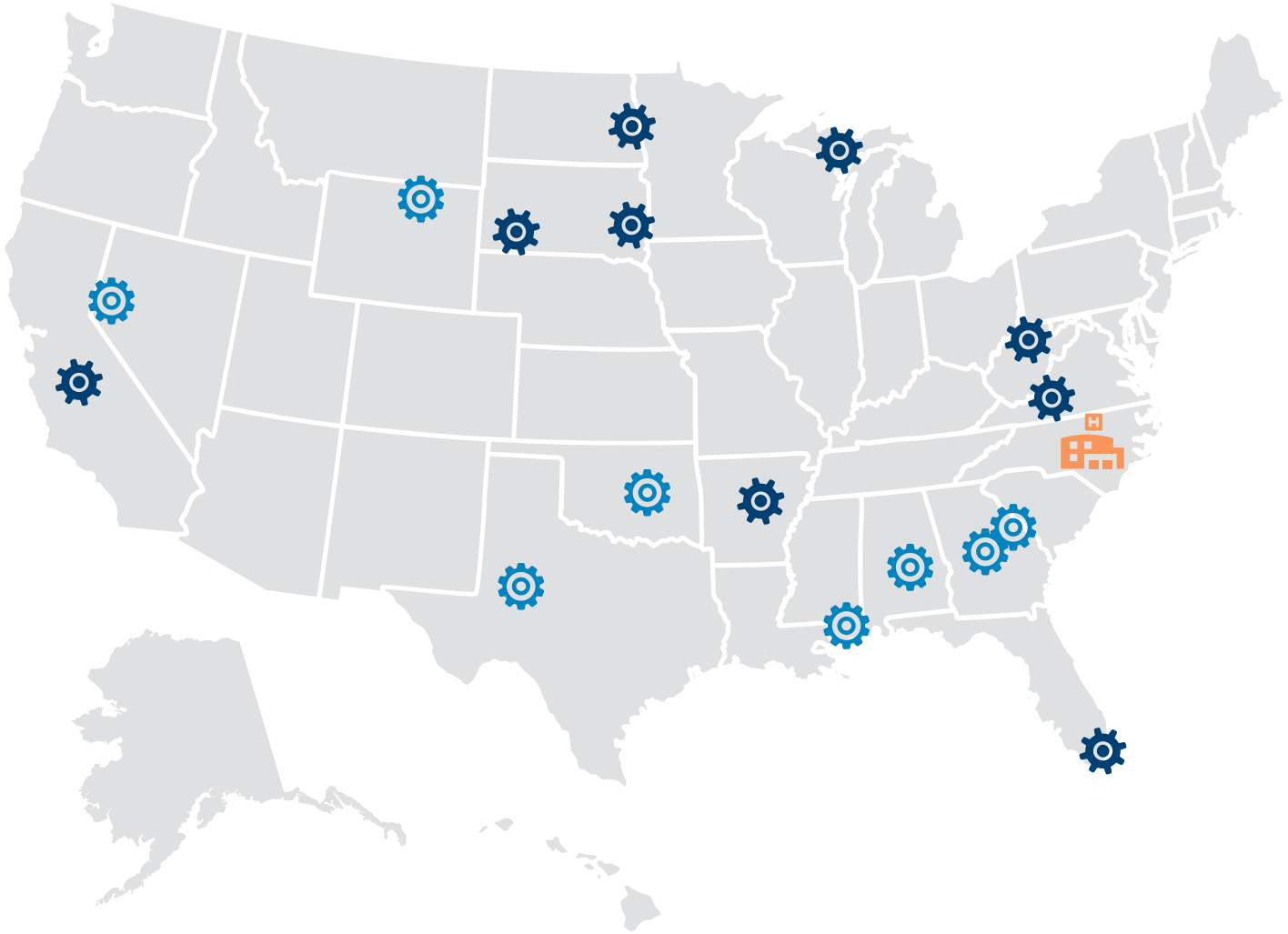
"They know we're going through a lot, the care teams have been wonderful, and Dr. Kelley is just great.

Roger and Henrietta Lupkes
U.S. Army Veteran

Hub and Spoke Site(s) Model



National TeleOncology Program



Spokes Activated

1) Sioux Falls
2) Clarksburg
3) Salem
4) Fayetteville, AR
5) Iron Mountain
6) Black Hills
7) Fresno
8) Miami
9) Fargo

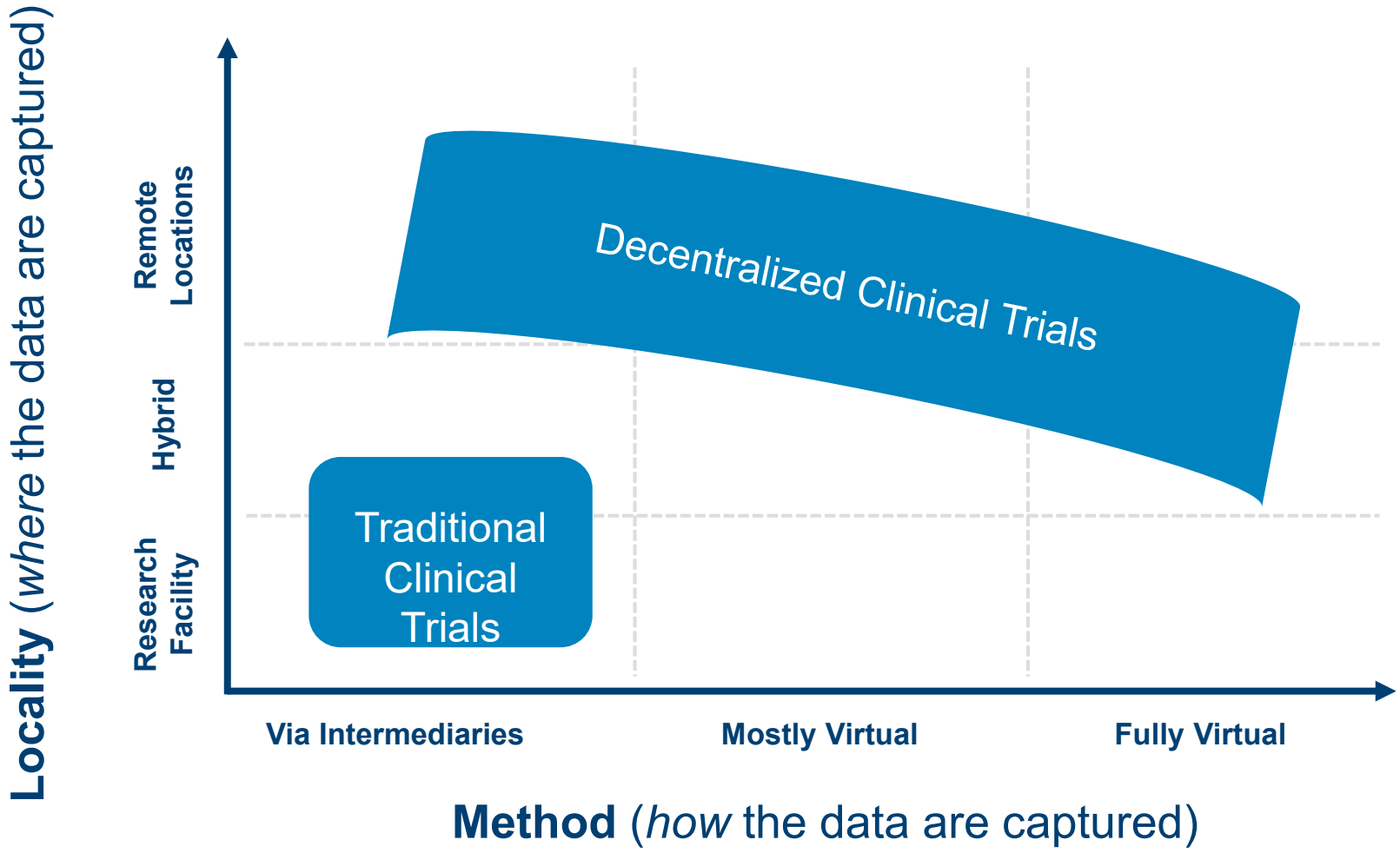
Spokes Initiated

1) Reno*
2) Central Alabama*
3) Sheridan*
4) Augusta*
5) Dublin*
6) Biloxi (Gulf Coast)
7) Muskogee, Oklahoma
8) Big Springs, TX

Durham Hub

*APP Funding from NTO

DCT Models: Where and How Data are Collected



Khozin S, Coravos A. Clinical Pharmacology & Therapeutics · April 2019 DOI: 10.1002/cpt.1441

Advantages of Decentralized Clinical Trials

Compared to site-based trials

- Cost substantially less
- Higher recruitment rate
- Higher retention rate
- Participants more diversity
- Clinical applicability more likely
- Digital tools provide more data

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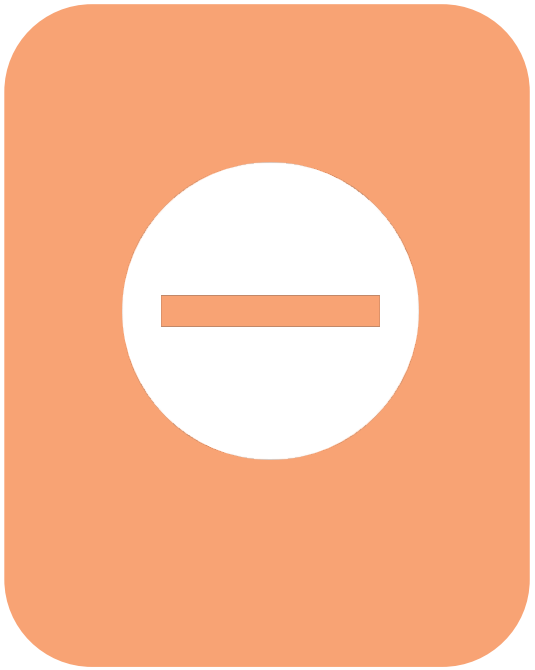
Limitations of Decentralized Clinical Trials



- Translational trials requiring research biopsies
- Frequent biosampling such as pharmacokinetic studies
- Registration studies
- Studies that do not qualify for FDA waiver

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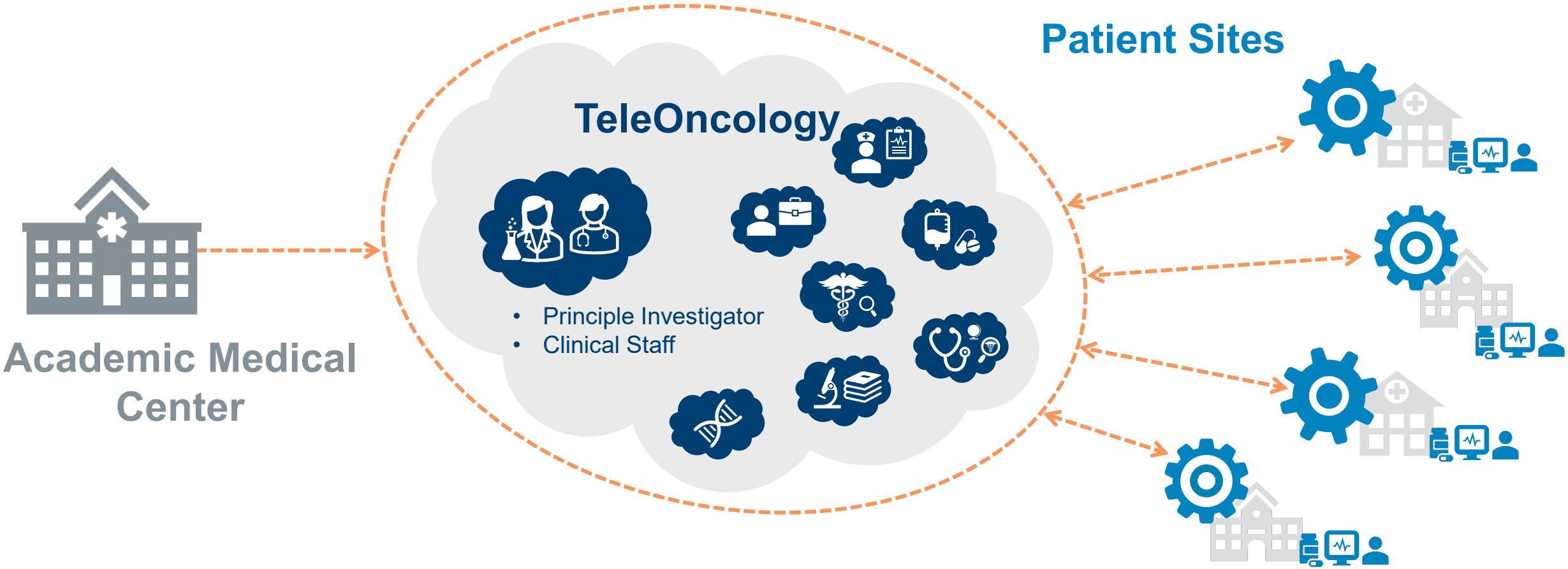
Virtual Clinical Trial Model



Cemiplimab Survivorship Epidemiology (CASE) Study

- Prospective phase IV study of cemiplimab in cutaneous squamous cell carcinoma
- Primary endpoints include:
  - Efficacy: ORR, DCR, DOR, time to response, PFS, OS, TTTF, disease specific death
  - Toxicity: irAEs, SARs, infusion-related reactions
  - Patient Reported Outcomes

Proof-of-Concept Decentralized Clinical Trial (POTENTIAL): Study Schema

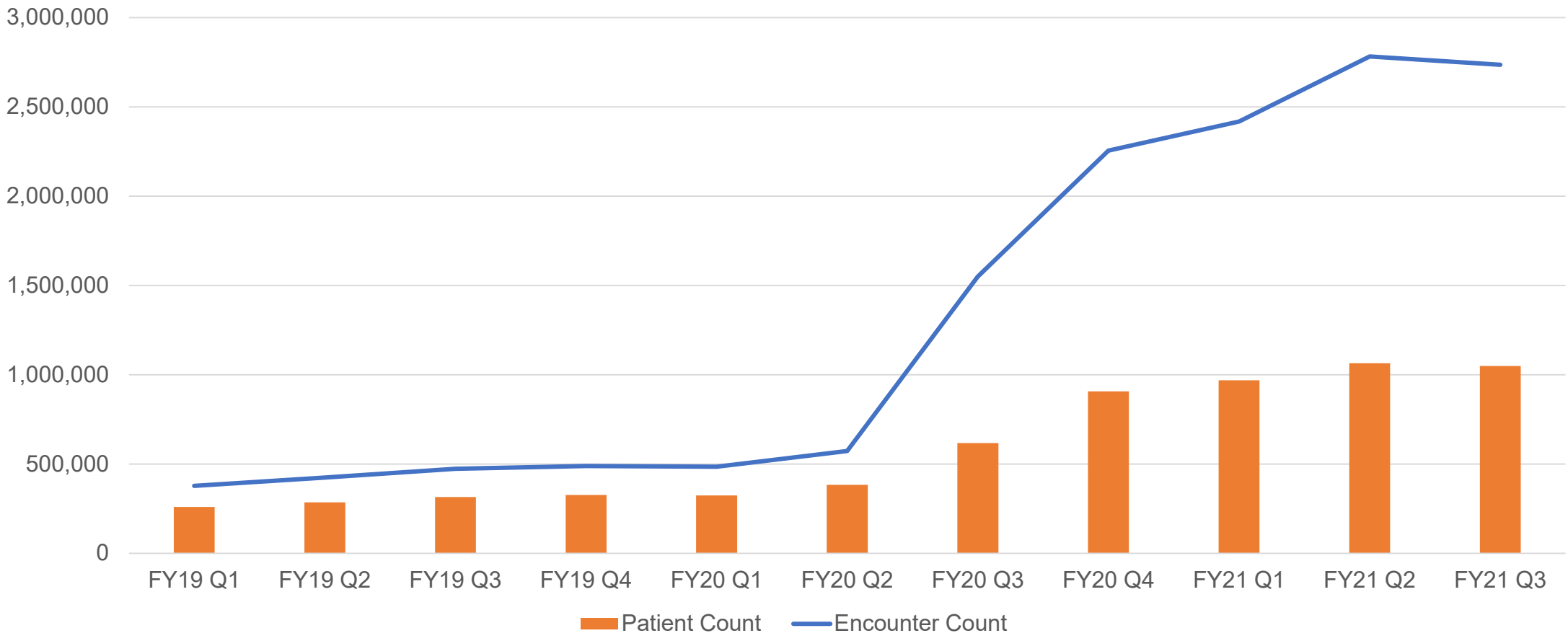
Selection Criteria

- Age >= 18
- Ability to comply with study protocol
- ECOG PS –2
- Technology-specific criteria
- Disease-specific criteria

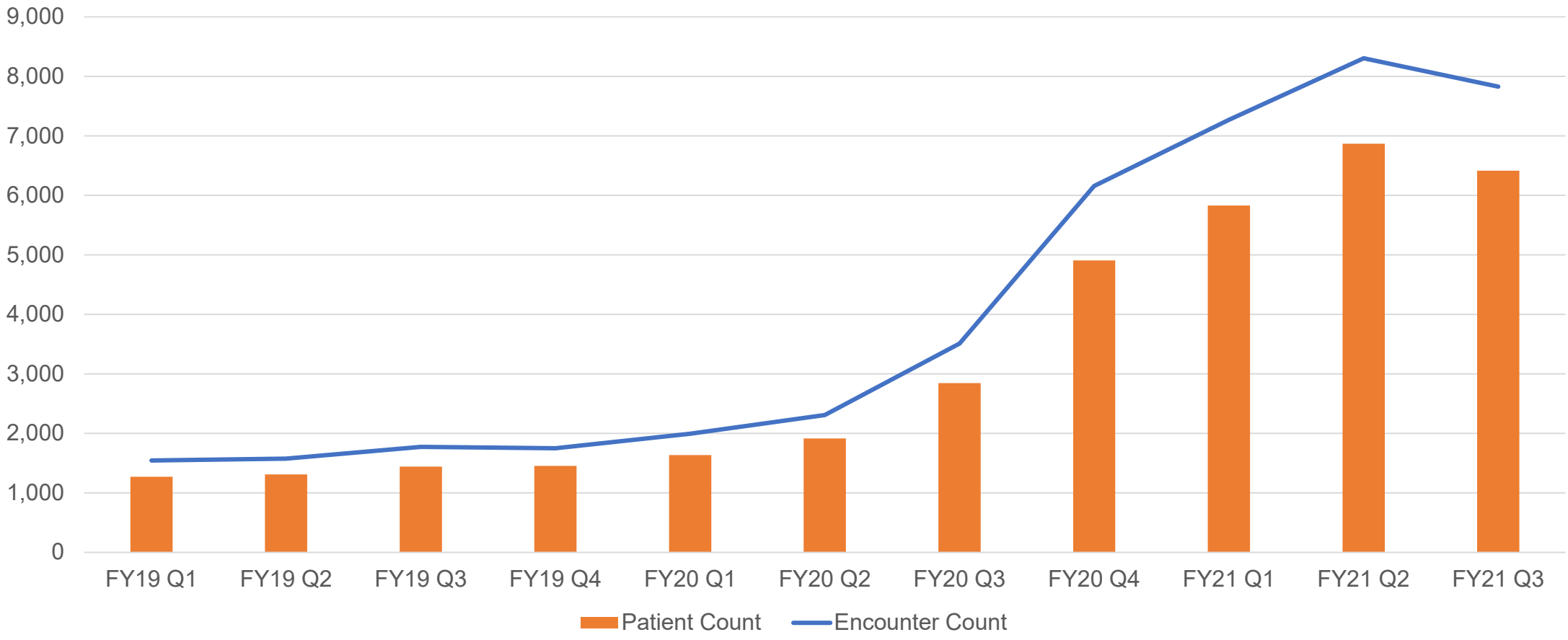
- DCT Consent (eConsent)
- Complete eConsent Questionnaire (1 question)
- Train patient on wearable and technology platform
- Individual standard treatment recommendation
  - mCRPC or mNSCLC
- Follow-up for 6 months
  - Medical records & wearable
  - Questionnaire at each visit (4 questions)
- Complete Exit Questionnaire
  - Patient 16 questions
  - HCP 4 questions

Source: Study protocol

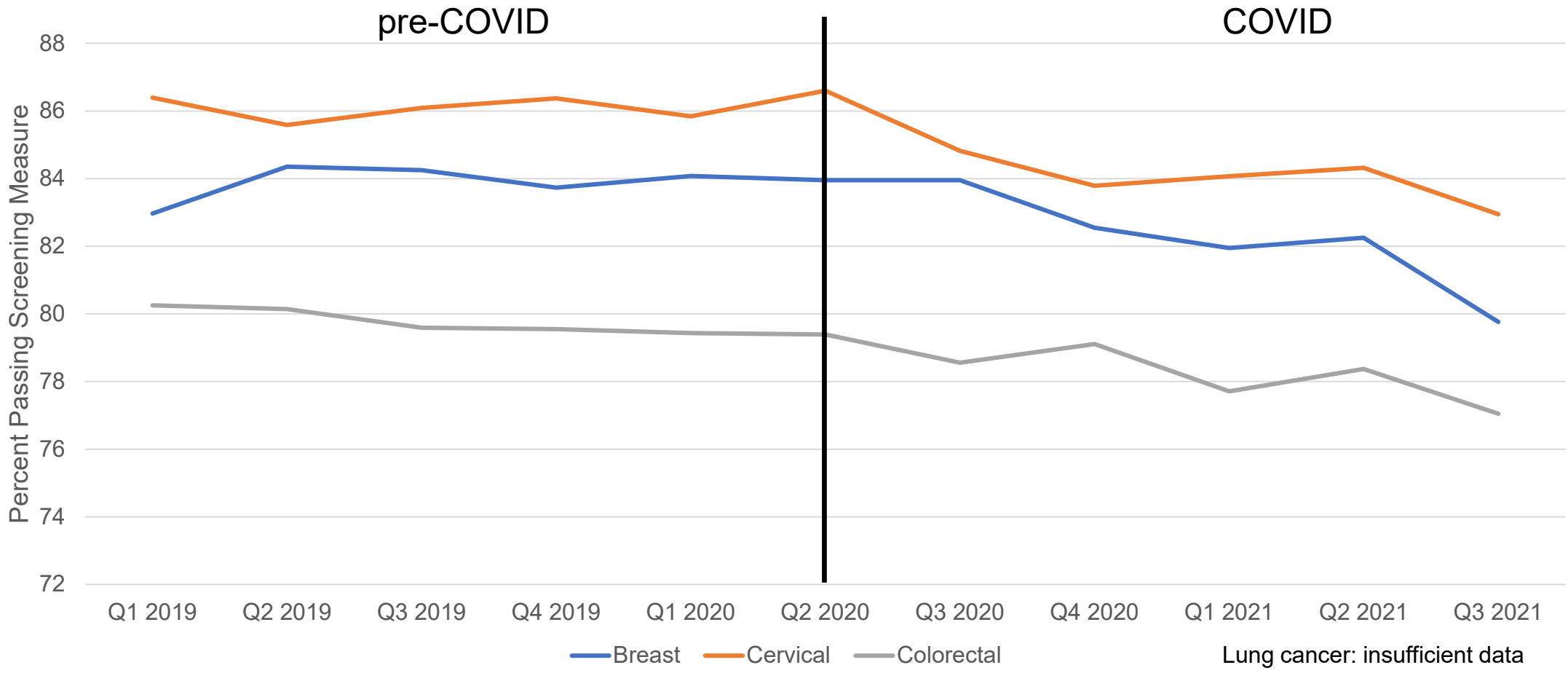
VA Overall Telehealth Patients and Visits



VA Overall Teleoncology Patients and Visits



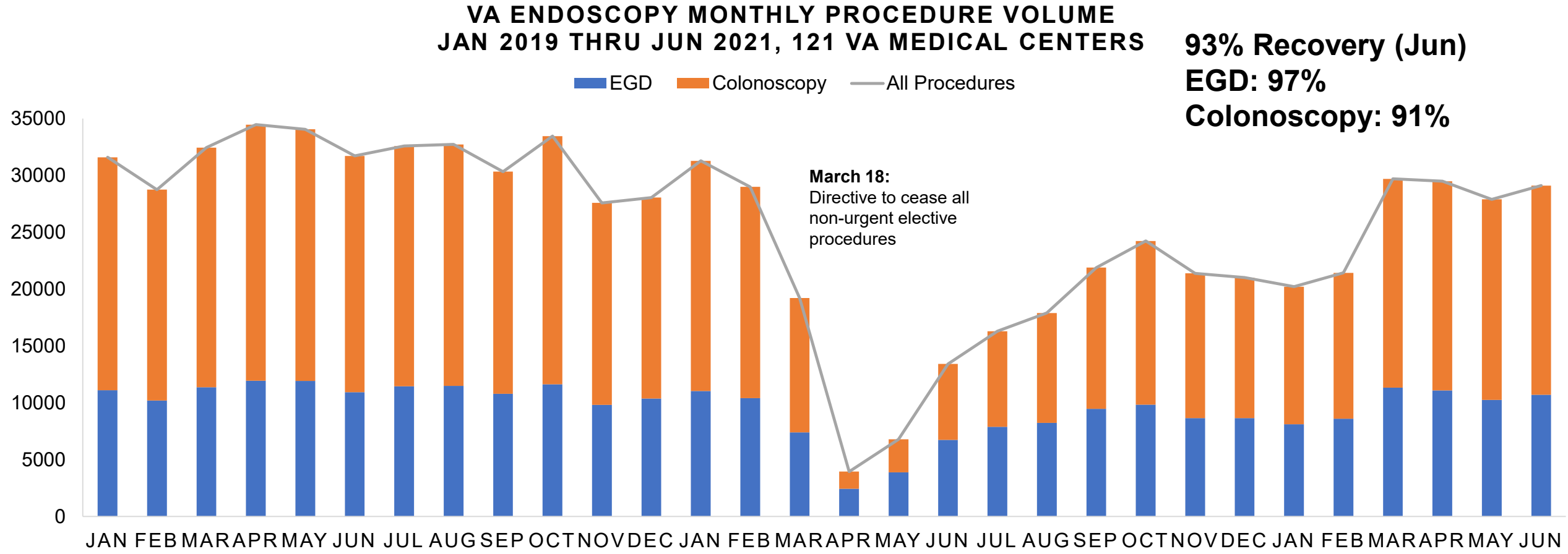
Cancer Screening Rates in VHA: 2019-2021



Lung cancer: insufficient data

COVID-19 Impact on Access to Endoscopy Procedures in VA

Gawron, AJ; Kaltenbach, T; Dominitz, JA *Gastroenterology,* 2020 Oct



Method of CRC Screening in VHA: 2019-2021

	3/15/2019 – 3/14/2020	3/15/2020 – 3/14/2021	Net Change	Percent Change
FIT Ordered	824,765	881,428	56,663	6.9%
FIT Resulted	399,031 (48.4%)	371,956 (42.2%)	(27,075)	(6.8%)
Colonoscopy	281,643	134,525	(147,128)	(52.2%)
Screening Colonoscopy	10,372	2336	(8036)	(77.5%)

New Anti-Cancer Drug Starts 2019-2020