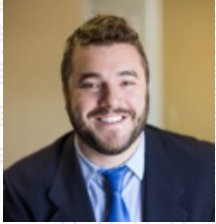


Oncology NOW:

What's Impacting Oncology Sites in 2021



Jimmy Bechtel, MBA
Vice President, Site Engagement
Society for Clinical Research Sites



Marcus Maleck
Director, Global Business Partnerships
Society for Clinical Research Sites



Sandy Smith, RN, MSN, AOC
Senior Vice President, Clinical Solutions
and Strategic Partnerships
WCG



Sean Soth
Vice President, Business Partnerships
Society for Clinical Research Sites



Global Oncology
Site Solutions Summit

PARTNERING FOR SUCCESS

SITESNOW →

February 23, 2021



Faculty Disclosure

- In compliance with ACCME Guidelines, I hereby declare:
- I do not have financial or other relationships with the manufacturer(s) of any commercial services(s) discussed in this educational activity.
- Sandra Smith, Senior Vice President, Clinical Solutions and Strategic Planning, WCG

Sites NOW @ Work!

Sites NOW: September 2020 Recap



COLLABORATE FORWARD

SCRS Welcomed 80 clinical research executives to the first Sites NOW program.



COLLABORATE FORWARD

Thank you to the SCRS Sites NOW Supporters & Featured Speaker:

Michael Jay

Director, Special Project, Society for Clinical Research Sites

Budgets & Contracts



Sites NOW Highlights Issues Impacting Site Operations in September Launch

"Our main goal here is collaboration towards information." With these impactful words, the first-ever SCRS Sites NOW session was launched. In a dynamic session that attracted more than 80 clinical executives, unreleased data and industry perspectives were shared freely in a virtual environment that emulated the face-to-face energy of past Site Solutions Summits.

Sites NOW is a virtual discussion and content project created in response to the COVID-19 pandemic and focused on the changing landscape clinical research sites and industry partners face in 2020.

Over the next 12 months, Sites NOW will provide a forum for content-sharing, open discussion, and networking among industry stakeholders, to include sites, sponsors, CROs, and solution providers. At each session, subject matter experts provide a 30-minute presentation focused on providing meaningful metrics and invaluable insight into one central theme impacting research today. Following the presentation, attendees participate in team breakout sessions to discuss industry standards, best practices, and pressing questions related to the presentation with the overall objective of providing information for site success.

While advancing site sustainability is the underlying mission of SCRS, Sites NOW delivers a platform to meet, share, and explore solutions that advance thoughts, best practices, and – most importantly – relationships.



WHO OWNS A STUDY?

The initial session tracked different industry perspectives on one central theme: why sites matter. Industry leader David Vulcano, vice president of clinical research at HCA Healthcare, kicked off the meeting by presenting new data from a recent SCRS Site Survey to convey the rich and varied perspectives on why sites matter in 2020. Mr. Vulcano provided a comprehensive overview of the evolution of the site and how its function has changed congruently with clinical trial format.

Sites NOW Pharmaceutical Supporters

abbvie

AstraZeneca 

Boehringer
Ingelheim

Bristol Myers Squibb™

gsk

janssen 
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

Lilly

Pfizer

Roche

SANOFI 

Sites NOW CRO Supporters



Sites NOW Solution Provider Supporters

Accellacare

ADVARRA

bio-optronics
Ensuring access to care

BlueCloud[®]
by HealthCarePoint

BRANY BREEZE[®]
Clinical Trial Solution[™]

Clinclerge

ClinEdge
bto NETWORK

clinical.ly

Complion[™]

CRI[®]
clinicalresearch.io

docutrial

Florence
HEALTHCARE

greenphire

hyperCORE
INTERNATIONAL
CENTERS OF RESEARCH EXCELLENCE

LedgerRun
ENGAGE SMART

MEDIDATA

Medix

ORACLE
Health Sciences

THE PATIENT[®]
RECRUITING
AGENCY
LOOK NO FURTHER

REALTIME
CLINICAL TRIAL MANAGEMENT SYSTEMS

ripple
science

ScienceMedia

Splash
Clinical
Innovative Patient Recruitment

STUDYXIK

SubjectWell

trialscout

trifecta

Veeva

VIRTRIAL
A SIGNANT HEALTH COMPANY

wcg

Global Oncology
Site Solutions Summit
PARTNERING FOR SUCCESS

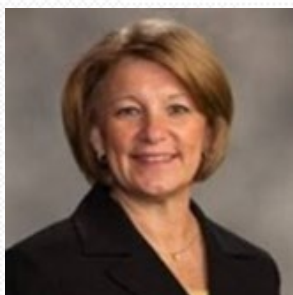
SITESNOW

#SCRS21Oncology



AGENDA

- 11:30-12:10 Intro and main presentation
- 12:10-12:40 Coffee Break Meet-ups and Team Breakouts
- 12:40-1:00 Team reporting in main room



Sandy Smith, RN, MSN, AOC
Senior Vice President, Clinical Solutions
and Strategic Partnerships
WCG


PRESENTATION AGENDA

- Current State of Oncology
- Impact of the Pandemic
- Outlook



Current State of Oncology

- Overall cancer mortality has decreased
 - Peak in 1991: 215 deaths/100,000
 - 2018: 149 deaths/100,000
- Progress: Lung, colorectal, breast, prostate
- **1,501** new cancer drugs approved by FDA since 2006



29%

2.9 Million Fewer Cancer Deaths

Cancer Incidence 2021

Estimated New Cases

				Males	Females				
Prostate	248,530	26%				Breast	281,550	30%	
Lung & bronchus	119,100	12%				Lung & bronchus	116,660	13%	
Colon & rectum	79,520	8%				Colon & rectum	69,980	8%	
Urinary bladder	64,280	7%				Uterine corpus	66,570	7%	
Melanoma of the skin	62,260	6%				Melanoma of the skin	43,850	5%	
Kidney & renal pelvis	48,780	5%				Non-Hodgkin lymphoma	35,930	4%	
Non-Hodgkin lymphoma	45,630	5%				Thyroid	32,130	3%	
Oral cavity & pharynx	38,800	4%				Pancreas	28,480	3%	
Leukemia	35,530	4%				Kidney & renal pelvis	27,300	3%	
Pancreas	31,950	3%				Leukemia	25,560	3%	
All Sites	970,250	100%				All Sites	927,910	100%	

Estimated Deaths

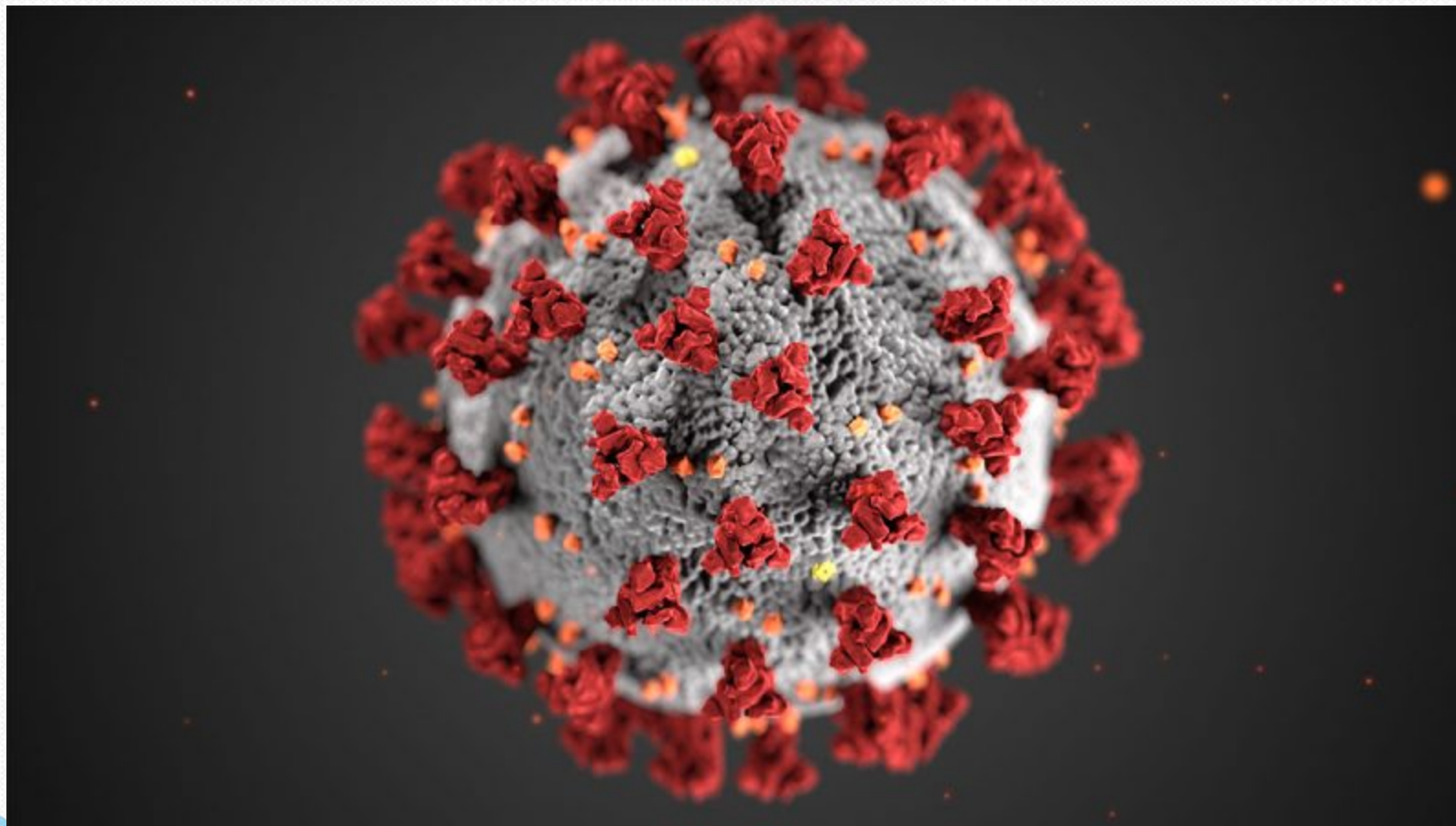
				Males	Females				
Lung & bronchus	69,410	22%				Lung & bronchus	62,470	22%	
Prostate	34,130	11%				Breast	43,600	15%	
Colon & rectum	28,520	9%				Colon & rectum	24,460	8%	
Pancreas	25,270	8%				Pancreas	22,950	8%	
Liver & intrahepatic bile duct	20,300	6%				Ovary	22,950	5%	
Leukemia	13,900	4%				Uterine corpus	12,940	4%	
Esophagus	12,410	4%				Liver & intrahepatic bile duct	9,930	3%	
Urinary bladder	12,260	4%				Leukemia	9,760	3%	
Non-Hodgkin lymphoma	12,170	4%				Non-Hodgkin lymphoma	8,550	3%	
Brain & other nervous system	10,500	3%				Brain & other nervous system	8,100	3%	
All Sites	319,420	100%				All Sites	289,150	100%	

Source: CA: A Cancer Journal for Clinicians, Volume: 71, Issue: 1, Pages: 7-33, 12 January 2021, DOI: (10.3322/caac.21654)

2021 Headlines

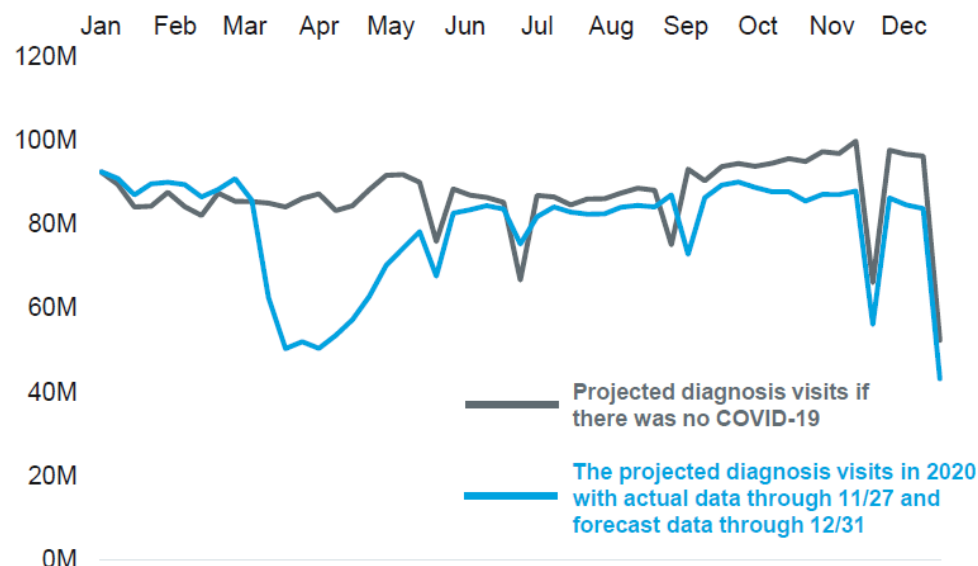
- **Breast cancer tops lung cancer as most diagnosed cancer in the world, new report says** (World Health Organization)
- **Colon and rectal cancer cases are going up among people younger than 50** (American Cancer Society)
- **Breast cancer rates have stopped declining in U.S. women younger than 40 years** (Radiology)

Impact of COVID-19



2020: Almost 1 Billion Diagnostic Visits Lost

Diagnosis Visit Gap Model: Actual Data Week Ending November 27, 2020



What is the “diagnosis visit gap”?

Difference between diagnosis visits¹ expected during a hypothetical non-COVID scenario and the number of diagnosis visits we actually see

COVID-19 Diagnosis Visit Backlog - w/e Nov 27, 2020; Source: IQVIA: Medical Claims Data Analysis, 2020, IQVIA Analysis

¹A diagnosis visit is for one single diagnosis per patient, per HCP; a patient can have more than one diagnosis visit assigned to them, with either more than one diagnosis per doctor or more than one doctor per diagnosis

Total Gap of Diagnosis Visits in 2020

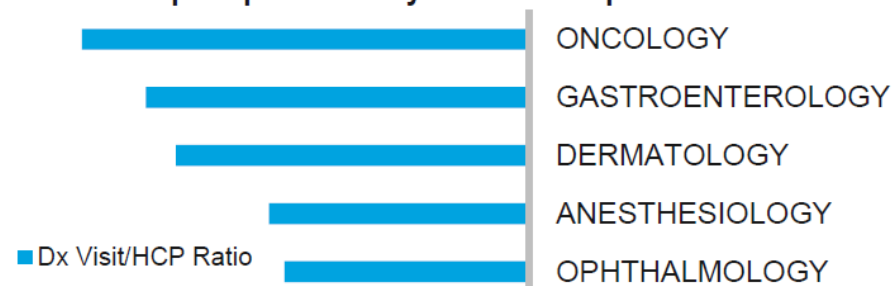
(Unique patient-provider diagnosis events)

-997M

% of Expected Diagnosis Visits in 2020

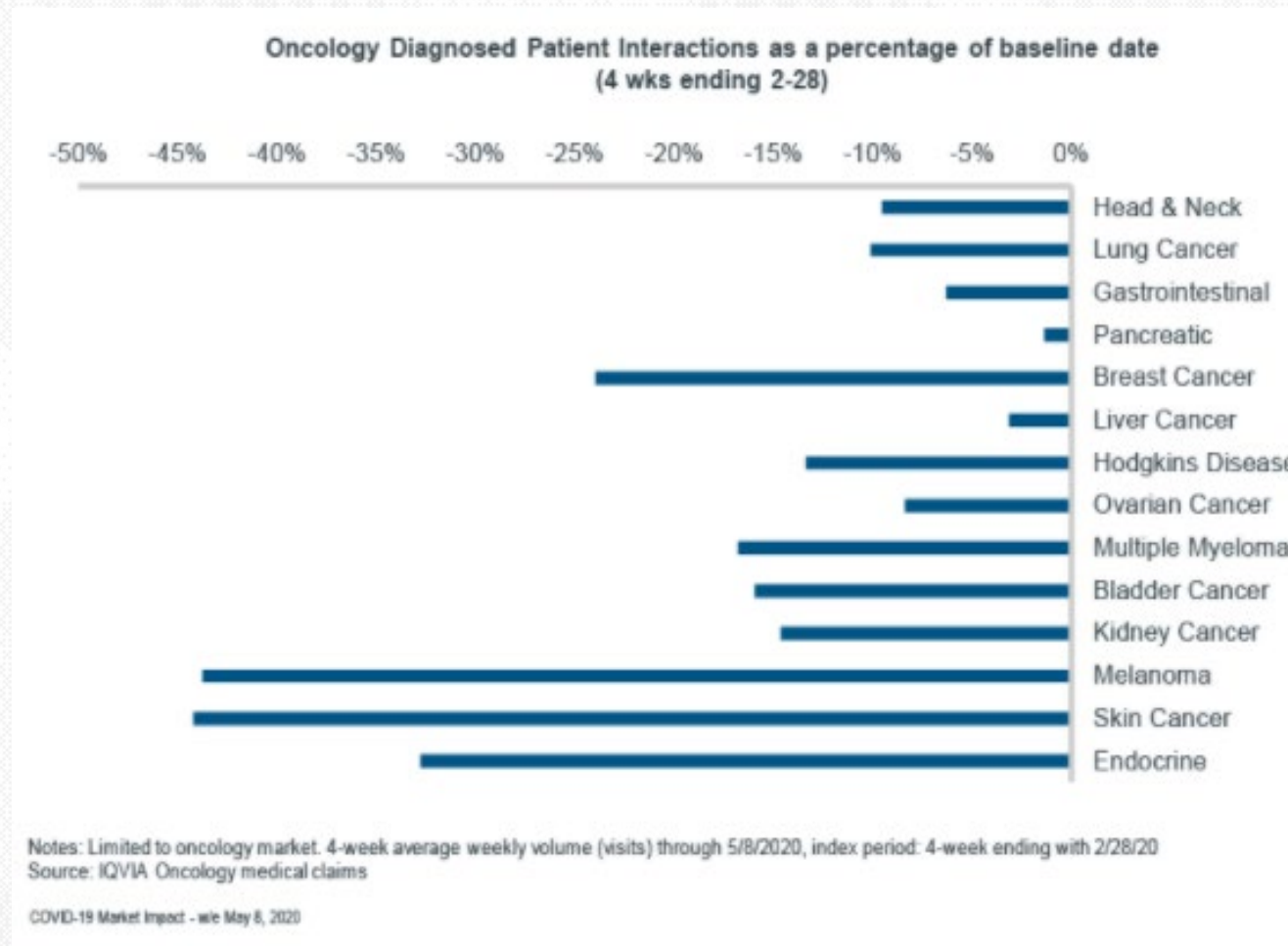
-30.0%

Top 5 Specialties by Dx Visits Gap/HCP



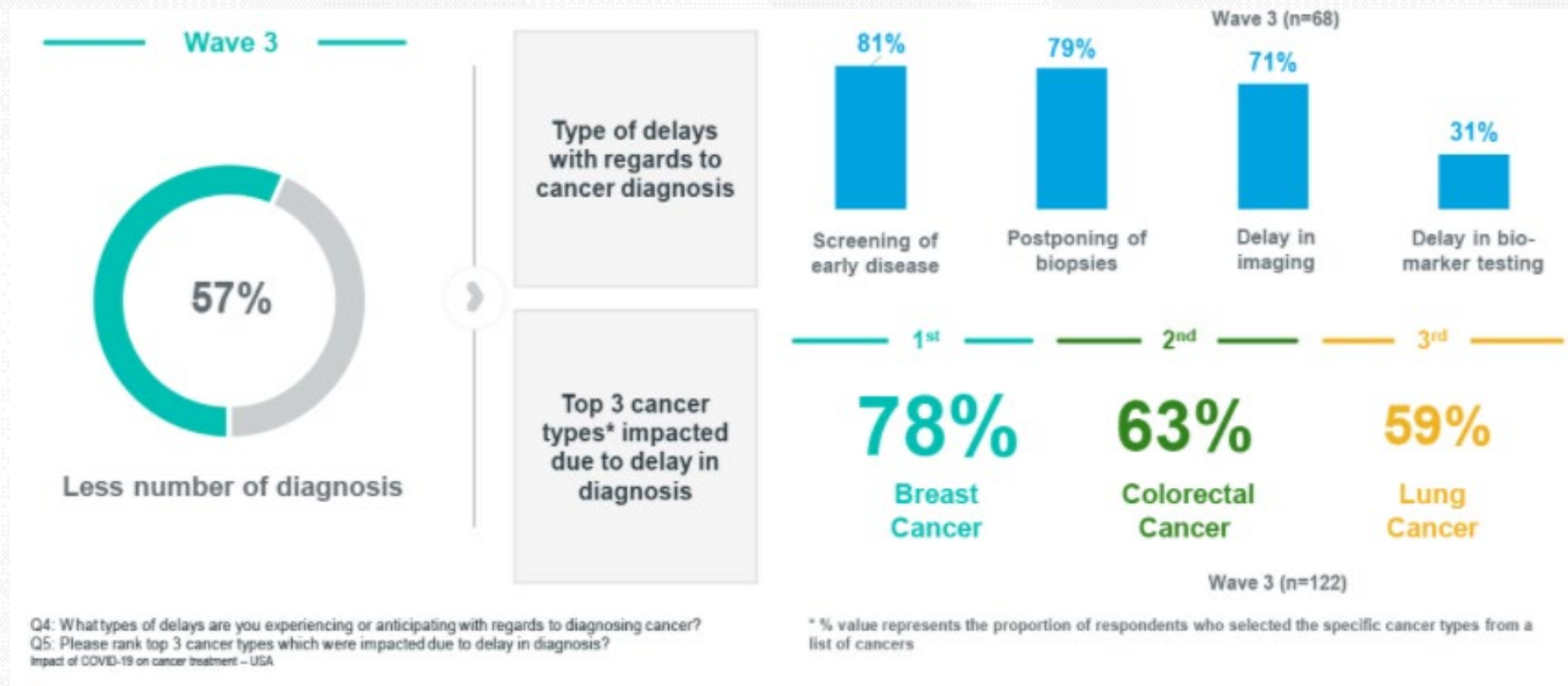
Source: IQVIA, Monitoring the Impact of COVID-19 on the US Pharmaceutical Market, February 12, 2021

Newly Diagnosed Patient Activity Falling (May 2020)



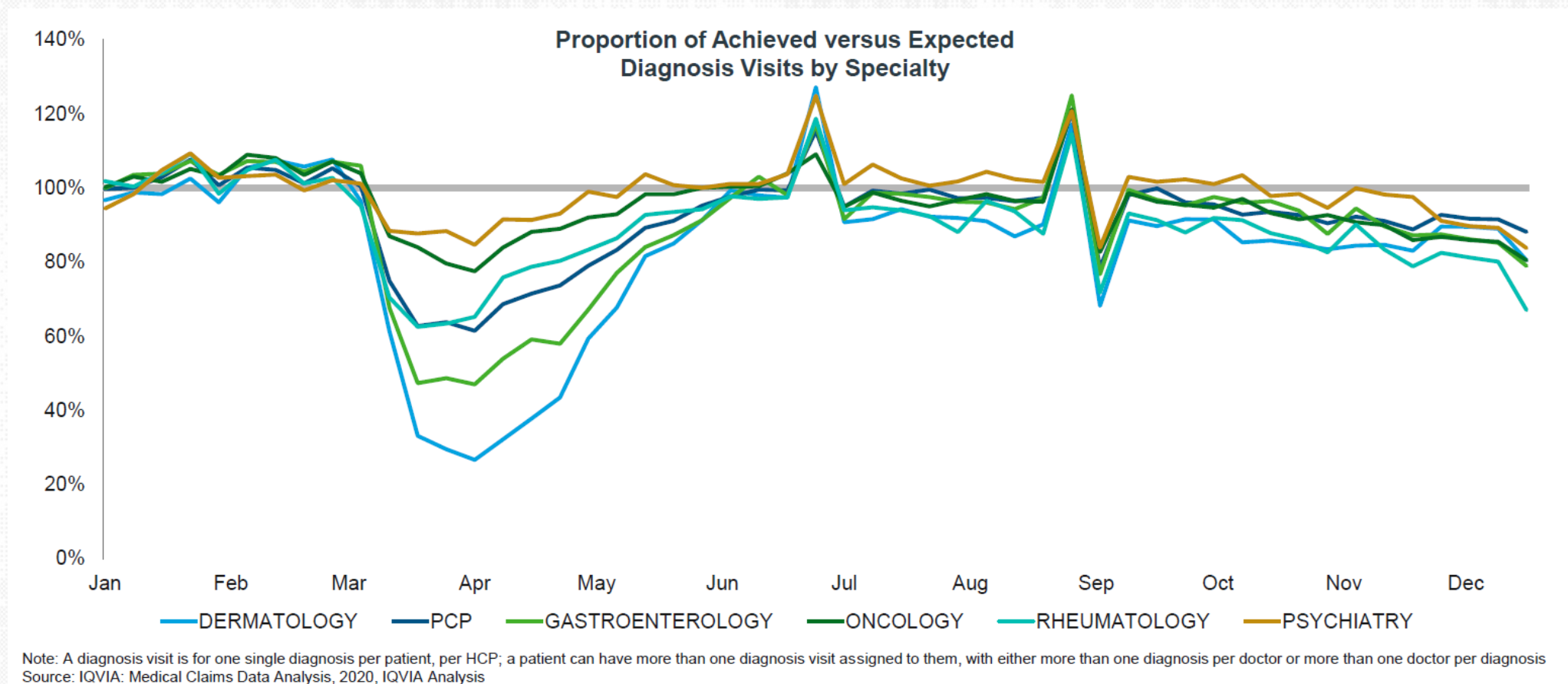
Source: IQVIA, The Reality of Lost Care - Monitoring the Impact of COVID-19 on the U.S. Pharmaceutical Market
February 18, 2021

Delays in Screening & Early Biopsies



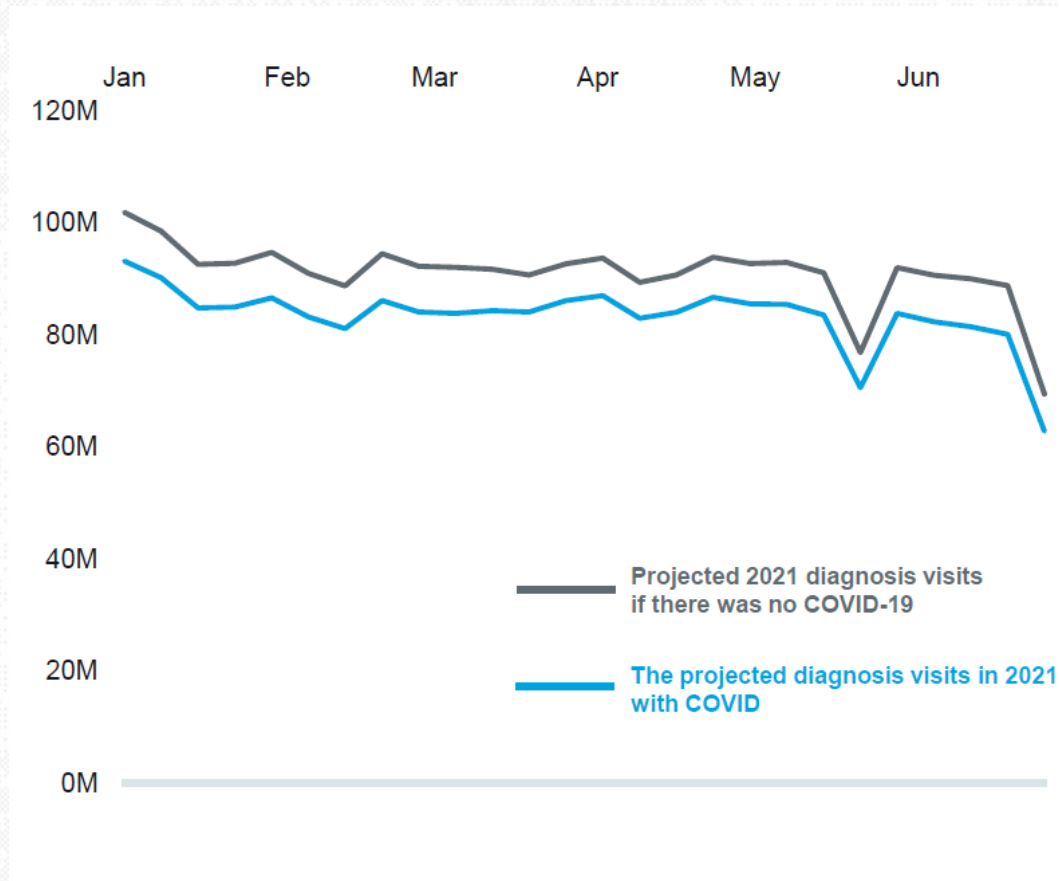
Source: IQVIA, The Reality of Lost Care - Monitoring the Impact of COVID-19 on the U.S. Pharmaceutical Market, February 18, 2021

Pandemic Impact on Medical Encounters



Source: IQVIA, The Reality of Lost Care - Monitoring the Impact of COVID-19 on the U.S. Pharmaceutical Market, February 18, 2021

Projection for 2021 Visits



Total projected
Diagnosis Visit
Gap in 2021

-206.7M

% of Expected
Diagnosis Visits
in 2020

-8.4%

Source: IQVIA, Monitoring the Impact of COVID-19 on the US Pharmaceutical Market, February 12, 2021



ASCO Clinical Cancer Advances: 2015-2020

2015

- Transformation of Treatment for CLL

2016

- Immunotherapy

2017

- Immunotherapy 2.0

2018

- Adoptive Cell Immunotherapy

2019

- Progress in Treating Rare Cancers

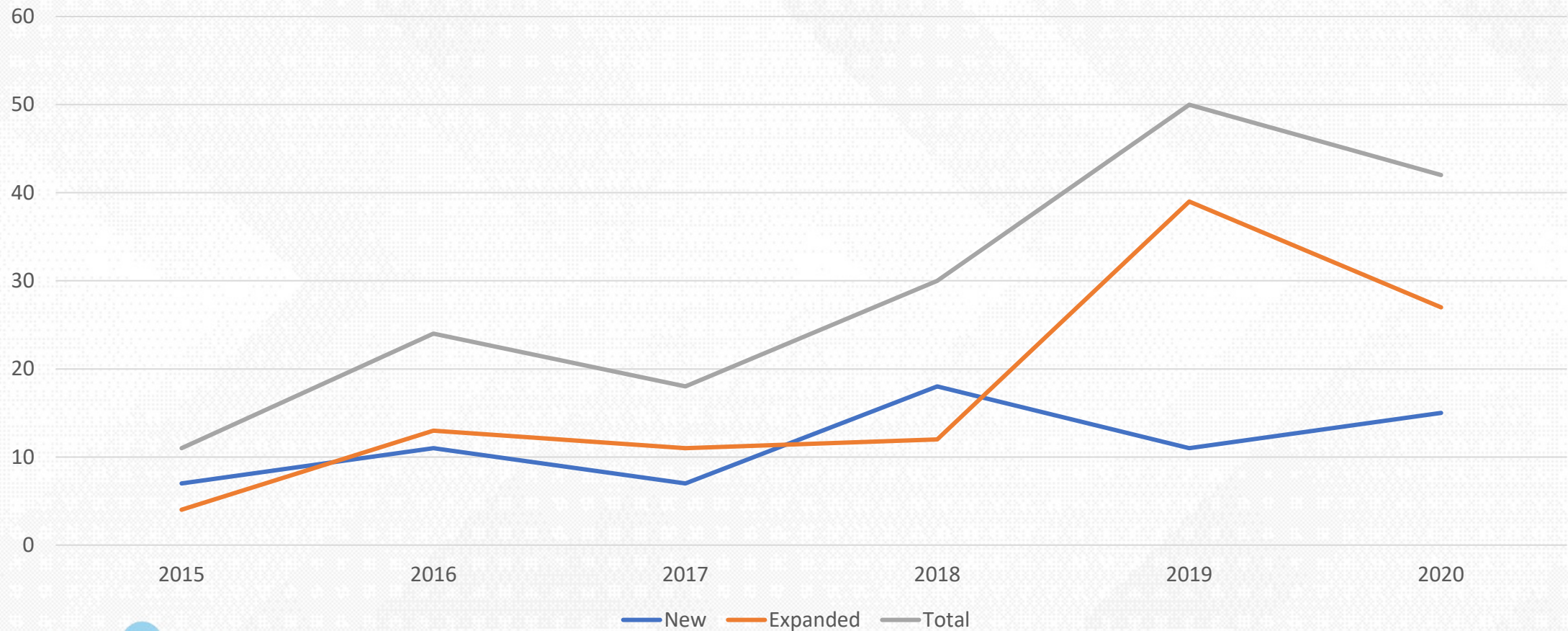
2020

- Refinement of Surgical Treatment of Cancer

ASCO 2021 Advance of the Year

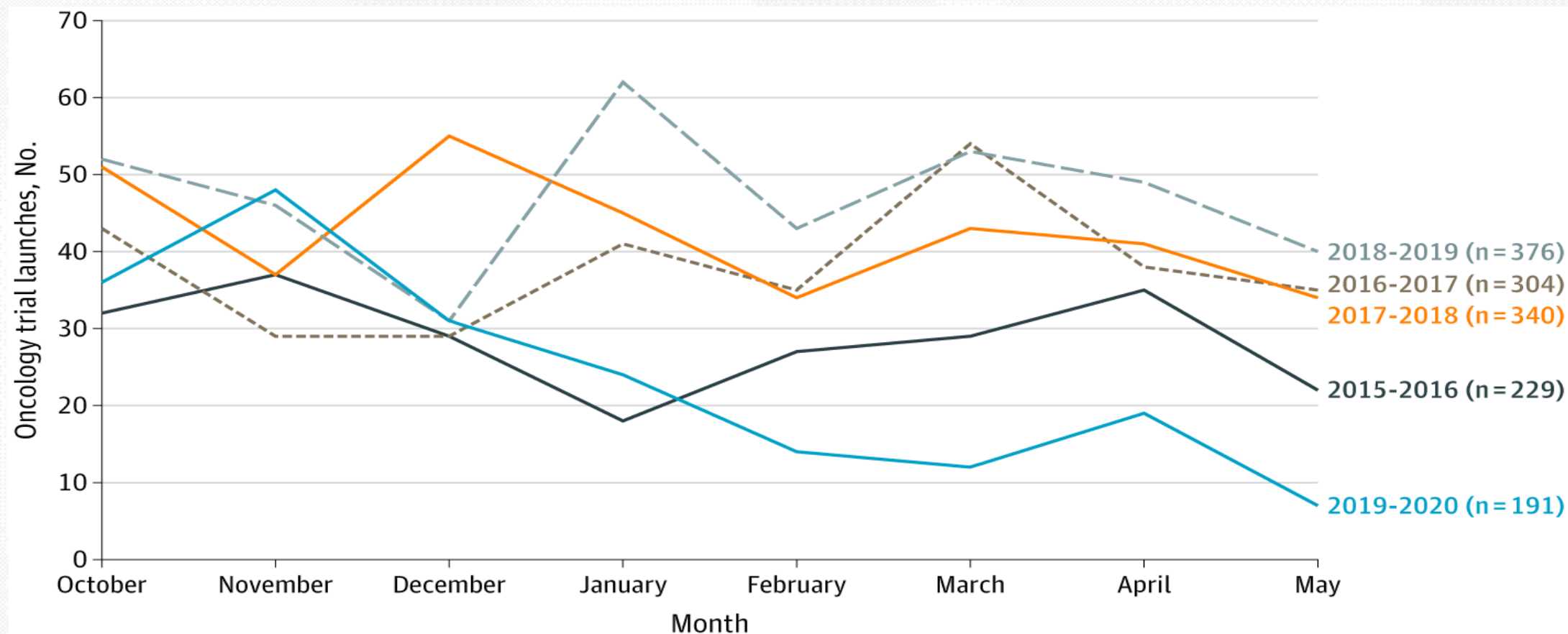
- Molecular Profiling in GI Cancers
- Additional Advances:
 - Progress in bringing targeted therapies to patients with earlier-stage disease.
 - Biomarker-driven treatment approaches that offer more personalized care for lung, colorectal, and gastric cancers.
 - Combinations of different therapies that extend survival without increasing toxicity.
 - A growing number of targeted therapies are offering extended survival for more patients with difficult-to-treat cancers.

FDA Oncology Approvals: 2015-2020

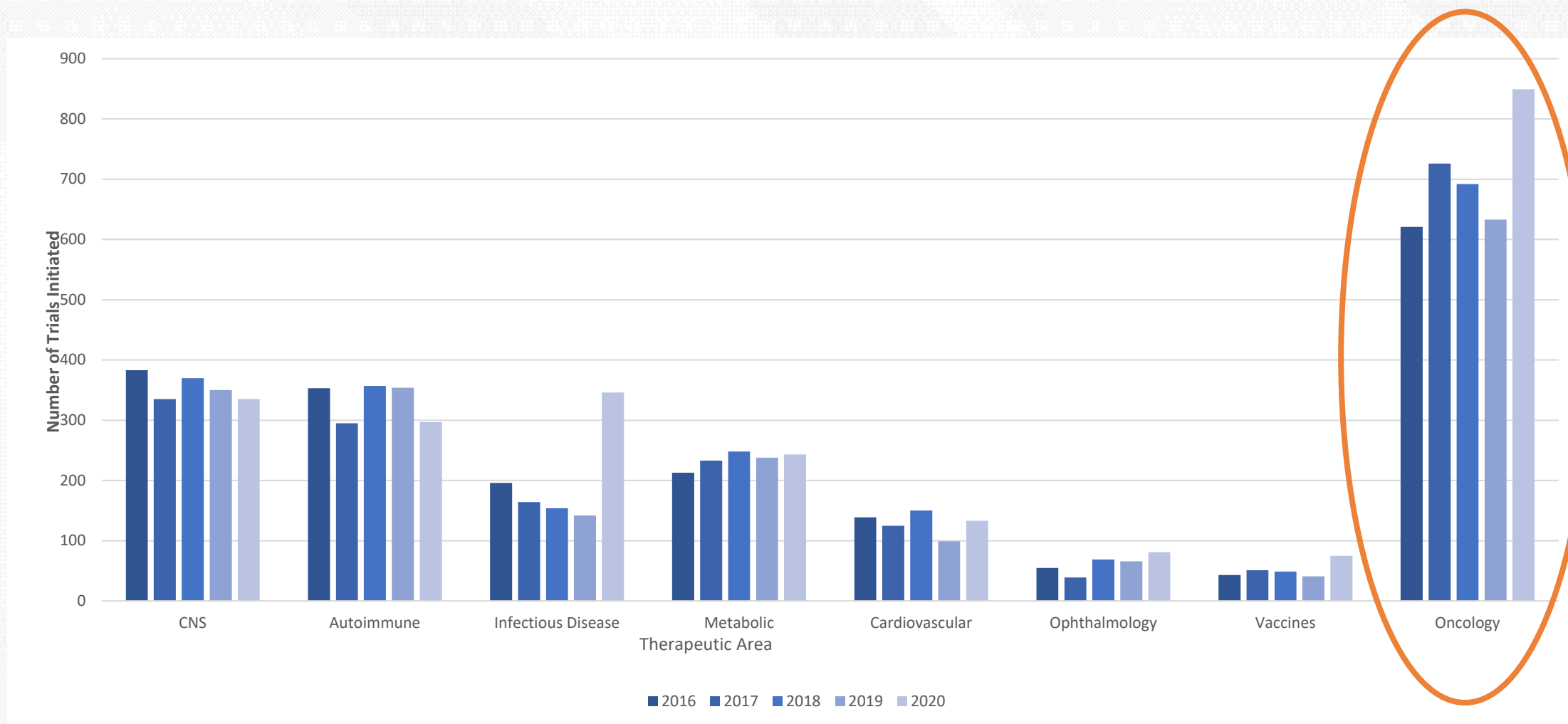


Source: ASCO website

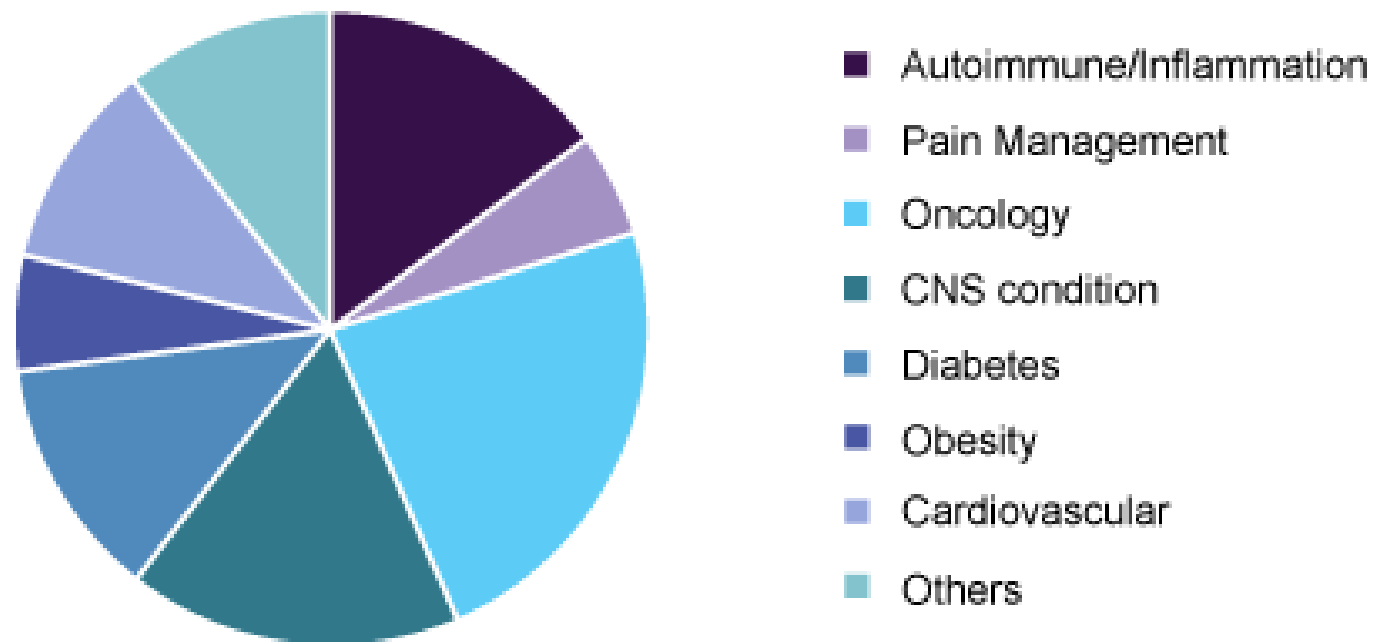
Changes in Numbers of Oncology Clinical Trials



Industry Trends by Therapeutic Area



Global Clinical Trials Market Share 2020



Source: Oncology Clinical Trials Market Size, Share & Trends Analysis Report, September 2020.
www.grandviewresearch.com

Trends Transforming Oncology Research

- Large pharma and biotech focusing on oncology
- Precision Medicine – Oncology pipeline is increasingly targeted:
 - Histology-agnostic approvals across multiple disease states (e.g., MSI-H; NTRK)
 - Continued expansion of molecular targets
 - Genomic understanding of carcinogenesis
- Multiple oncology therapies target the same molecular pathways
- Multiple agents are now tested against even rare tumors
- Next Generation Sequencing (NGS) & other companion diagnostics
- Expansion of cell and gene therapies
- Trial Designs: Adaptive trial designs, Synthetic arms
- Digitization: Seamless technology/AI integration
- Patient engagement in clinical trials

ASCO Research Priorities for 2021

- Develop and integrate AI/deep learning into cancer research
- Identify strategies that predict response and resistance to immunotherapies
- Optimize multimodality treatment for solid tumors
- Increase precision medicine in research and treatment approaches in pediatric and rare cancers
- Optimize care for older adults with cancer
- Increase equitable access to cancer clinical trials
- Reduce adverse consequences of cancer treatment
- Reduce obesity's impact on cancer incidence and outcome
- Better identify potentially malignant lesions and predict when treatment is needed

Achieving Equity in Cancer Research

As clinicians, we are committed to providing evidenced-based, high-quality cancer care to every patient, every day, everywhere. But, if clinical trials don't represent the individuals we treat, including those from racial, ethnic, and other minority populations, the state of science suffers, and patients with life-threatening conditions may not receive the best—perhaps only—treatment option for their condition.

—Lori J. Pierce, MD, FASTRO, FASCO, ASCO President, 2020-2021

Strategies to Achieve Equity

- Eligibility criteria
- Basket and umbrella trial designs
- Trial availability
- Patient education, recruitment, and support
- Patient navigation
- Novel consent strategies
- Financial assistance

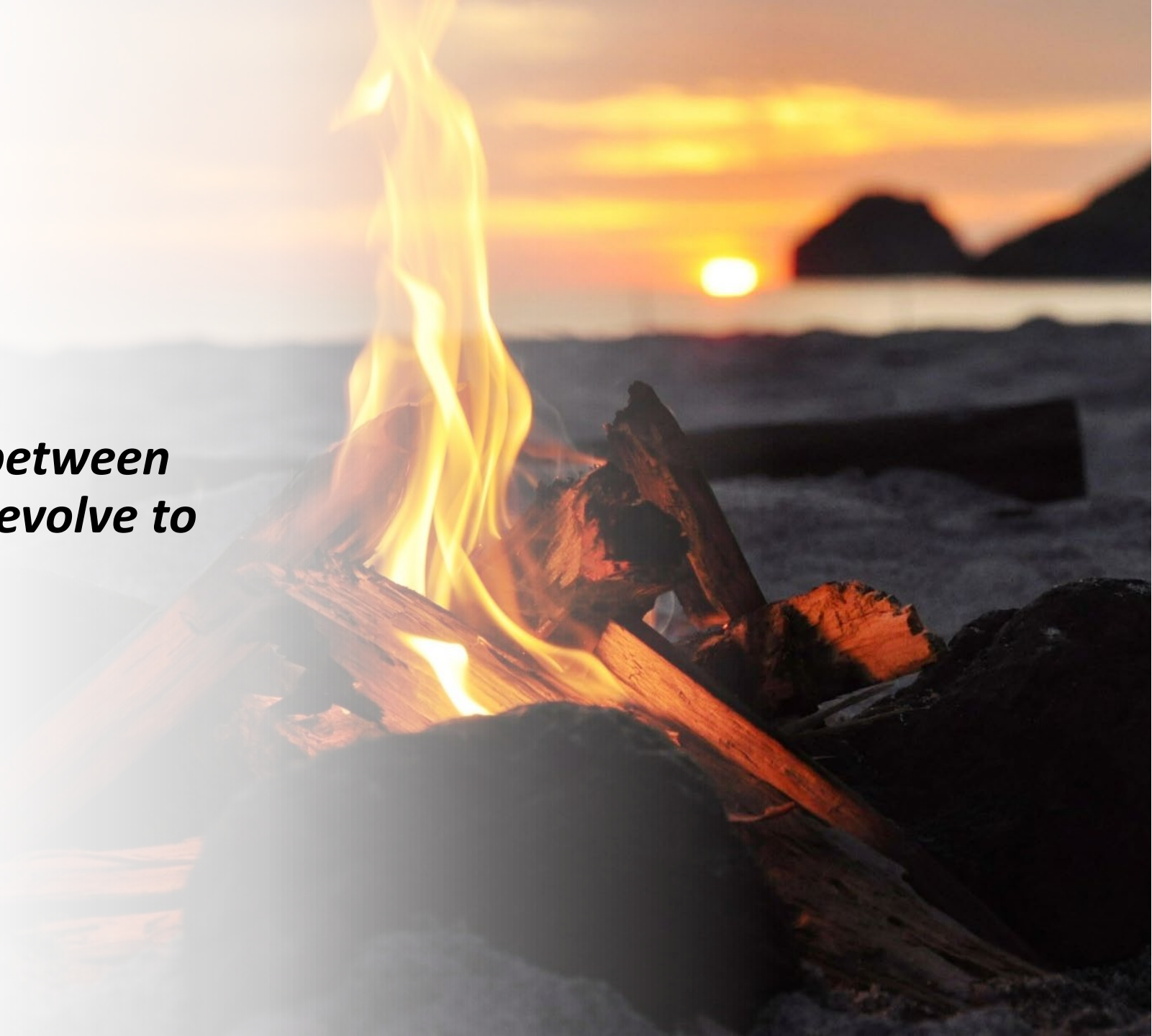
2021: This is our time!

Thank you!



Team Talk Firestarter

How can the collaboration between oncology sites and industry evolve to improve outcomes now?



Team Talks!

POPCORN!

***CHAT YOUR NAME, COMPANY,
and.....***

