

Targeting the Gut Microbiome to Promote Response and Mitigate Toxicity to Immunotherapy

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Society for Immunotherapy of Cancer Advances in Cancer Immunotherapy – A Focus on Toxicity Management Future Directions for Research and New Management Approaches in Immunotherapy Toxicities April 28, 2022

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Disclosure information

Advances in Cancer Immunotherapy – A Focus on Toxicity Management

Thursday April 28, 2022

Targeting the Gut Microbiome to Promote Response and Mitigate Toxicity to Immunotherapy

Jen Wargo

I have the following financial relationships to disclose:

Speaker's bureau / advisory boards: Imedex, Dava, Omniprex, Illumina, BMS, Roche – Genentech, GSK, Novartis, Astra-Zeneca, PeerView, Micronoma, Ella Therapeutics, Gilead Stock options: Micronoma

-and-

I will discuss the following off label use and/or investigational use in my presentation: *Microbiome modulation strategies* ty for Immunotherapy of Cancer #LearnACI



Thank you to everyone who contributed to this work!

Patients and families, all care providers, Melanoma Moonshot team, research teams and PRIME-TR, MD Anderson Cancer Center leadership, supporters and collaborators worldwide







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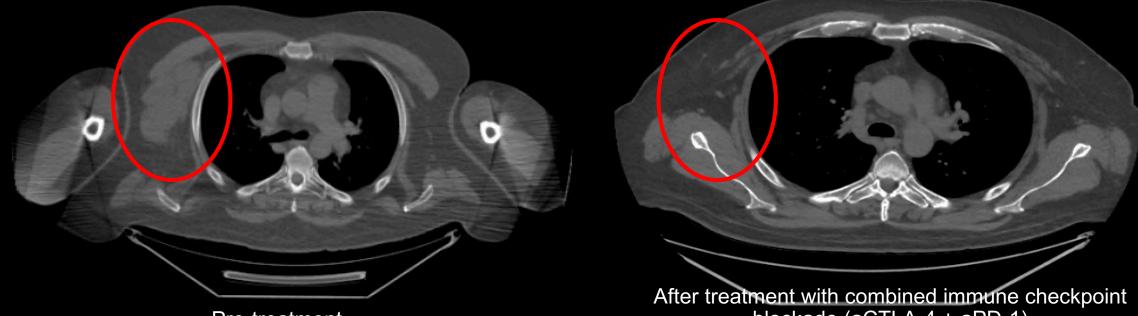
Targeting the Gut Microbiome to Promote Response and Mitigate Toxicity to Immunotherapy

- I. Background and evidence that gut microbes can promote response to cancer immunotherapy
- II. The role of gut microbes in mediating toxicity to immunotherapy
- III. Understanding other factors that influence gut microbes and response (and toxicity) to treatment (with opportunities to target these)

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Treatment with immunotherapy can be very effective in treating solid tumors However, treatment with immunotherapy may also be associated with toxicity

44 yo male with a history of multinodular goiter developed locoregional metastatic melanoma and was treated with neoadjuvant combined immune checkpoint blockade



Pre-treatment

blockade (aCTLA-4 + aPD-1)

During treatment he developed thyrotoxicosis and lost 50 lbs then was profoundly hypothyroid, with enlargement of his thyroid and tracheal compression with a delay in surgery (with a likely lifelong need for thyroid replacement hormone)



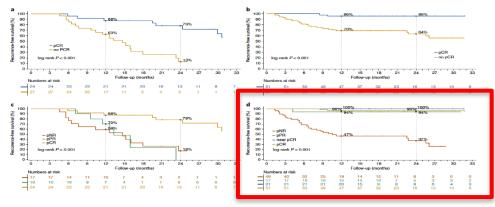
ARTICLES

Treatment with neoadjuvant immune checkpoint blockade is associated with benefit in most patients with melanoma treated (and now in other cancer types)

medicine

Pathological response and survival with neoadjuvant therapy in melanoma: a pooled analysis from the International Neoadjuvant Melanoma Consortium (INMC)

Alexander M. Menzies^{1,2,3,12}, Rodabe N. Amaria^{® 4,12}, Elisa A. Rozeman^{5,12}, Alexander C. Huang^{® 4,712}, Michael T. Tetzlaff^{4,12}, Bart A. van de Wiel^{5,17}, Serigne Lo^{® 1,2,12}, Ahmad A. Tarhini⁸, Elizabeth M. Burton⁴, Thomas E. Pennington^{1,2,2}, Robyn P. M. Saw^{® 1,2,2}, Xiaowei Xu⁶, Giorgos C. Karakousis⁶, Paolo A. Ascierto^{® 10}, Andrew J. Spillane^{® 1,2,3}, Alexander C. J. van Akkooi⁵, Michael A. Davies^{© 4,13}, Tara C. Mitchell^{® 4,13}, Hussein A. Tawbi^{© 4,13}, Richard A. Scolyer^{® 1,2,11,13}, Jennifer A. Wargo^{® 4,13}, Christian U. Blank^{® 5,13} and Georgina V. Long^{® 1,2,3,13}



medicine

LETTER:

Survival and biomarker analyses from the OpACIN-neo and OpACIN neoadjuvant immunotherapy trials in stage III melanoma

E. A. Rozeman¹, E. P. Hoefamitto^{3,17}, I. L. M. Reljers^{1,7}, R. P. M. Saw^{3,4,4}, J. M. Varsluis¹, O. Krijgsman^{2,4}, P. Dimitriadis^{3,7}, K. Sikorska¹, B. A. van de Wiel⁹, H. Eriksson^{10,10}, M. Gonzalez¹, A. Torres Acosta², L. G. Grijpink-Ongering¹, K. Shannon^{3,1,2}, J. B. A. G. Haanen^{1,2,4,3}, S. Chrig^{1,4,5}, O. E. Nieweg^{3,4,4,4}, H. A. Mallo¹, S. Adriaansz¹, R. M. Kerkhoven¹, S. Cornelissen^{1,4}, A. Broeks¹⁰, W. M. C. Klop^{1,4}, C. L. Zuu^{2,1}, W. Jvan Houdt¹, D. S. Peeper^{3,4,4}, J. Spiilane^{3,4,4,4}, A. G. J. van Akkool¹, R. A. Scolyer^{3,4,4,4}, T. N. M. Schumacher^{3,2,4}, A. M. Menzies^{3,4,6}, G. V. Long^{3,4,6} and C. U. Blank^{1,5,4,4}

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Menzies et al, Rozeman et al, Nature Medicine 2021

MELANOMA palpable lymph nodes

- Nivolumab 3 + ipilimumab 1: 70% pathologic CR!!
- No more TLND in >50% of patients with palpable nodes in 5 years

BLADDER CANCER

- 50% pCR for T3 bladder cancers: wait and see
- · Reduction cystectomies

MSI COLORECTAL CANCER

- 19/20 pCR for MSI CRC! (Haanen et al. Nature Medicine. 2020)
- In future in case of pCR: NO surgery, but endoscopy + MRI

LUNG, HEAD and NECK, ESOPHAGEAL and GASTRIC, BREAST, GBM

There is a still a critical need to improve responses to immunotherapy (and limit toxicity) in patients with established cancer, and opportunities to intercept & prevent cancer altogether

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How can we better understand responses to therapy

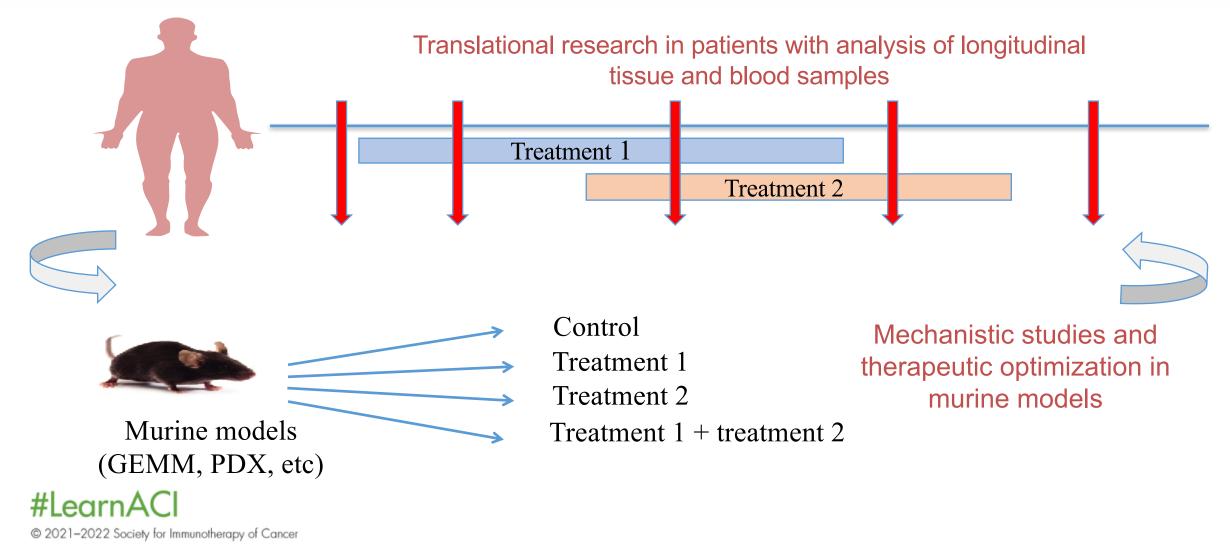
(as well as treatment-related toxicity)?





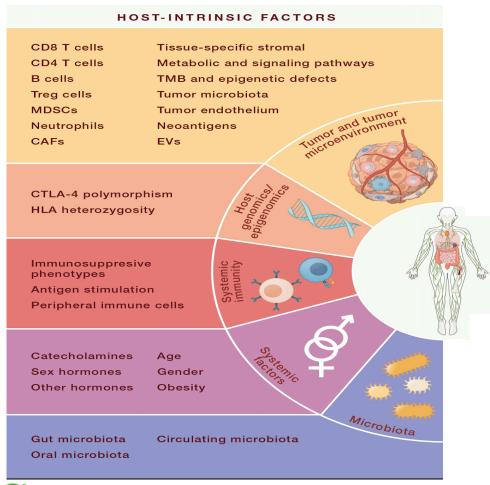
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A powerful way to better understand responses is via "reverse translation" – where findings go from bedside to bench, and back again





Through these types of approaches, we have identified a number of factors that impact tumor growth and response to cancer treatment that may be targeted



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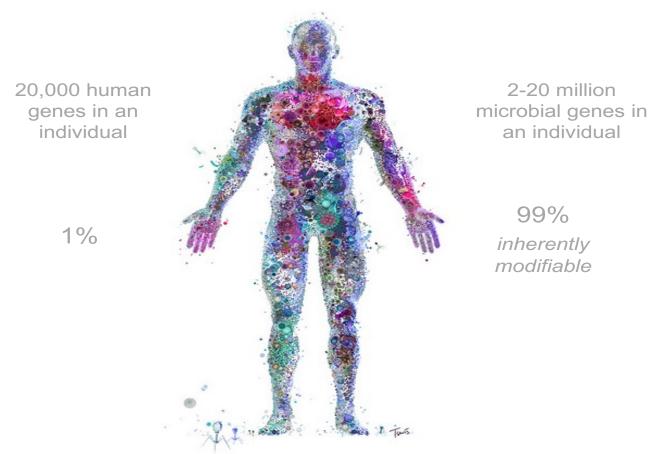
Morad et al, Cell 2021



3.5 billion years ago, microbes helped to shape the earth for future forms of life...



3.5 billion years later, it is now clear that microbes are pervasive in our environment (and within living organisms)

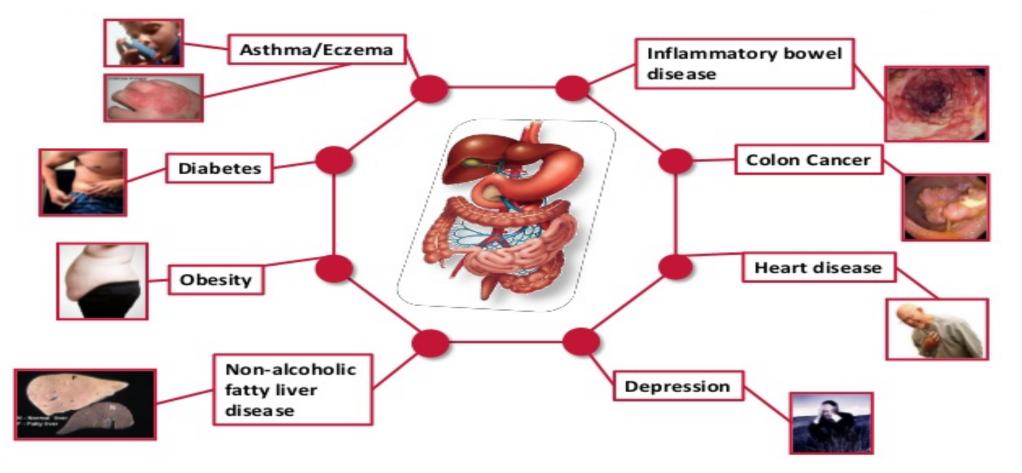


#LearnACI © 2021–2022 Society for Immunotherapy of Cancer Advances in next-generation sequencing have allowed us to better understand these microbes



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Disturbances of the gut microbiome (dysbiosis) are implicated in a large number of diseases

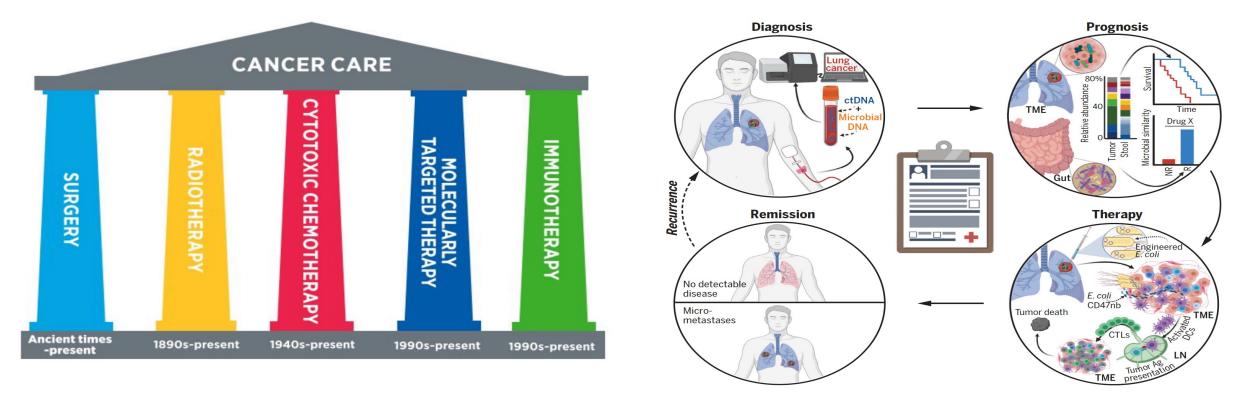


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Could microbiome targeting become the next "pillar" of cancer care?

With strategies to monitor and modulate the microbiome to treat, intercept, and perhaps even prevent cancer altogether?



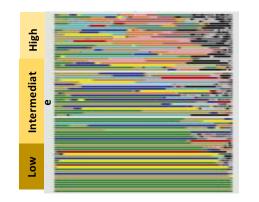
Sepich-Poore et al, Science 2021

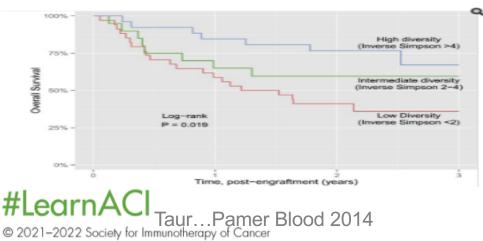
From AACR Cancer Progress Report



The gut microbiome may influence responses to SCT and checkpoint blockade

<u>Diversity</u> of the gut microbiome is associated with differential outcomes in the setting of stem cell transplant in patients with AML

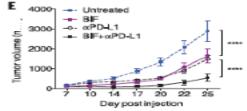




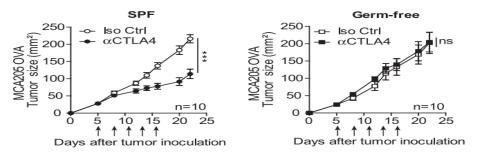
<u>Composition</u> of the gut microbiome is associated with differential responses to checkpoint blockade in murine models

Commensal *Bifidobacterium* promotes antitumor immunity and facilitates anti-PD-L1 efficacy

Ayclet Sivan,^{1*} Leticia Corrales,^{1*} Nathaniel Hubert,² Jason B. Williams,¹ Keston Aquino Michaels,² Zachary M. Earley,² Franco W. Benyannin,⁴ Yuk Man Lei,² Bana Jabri,⁶ Maria-Luisa Alegro,⁵ Ensione B. Chang,⁵ Thomas F. Gajewski^{1,3}⁺



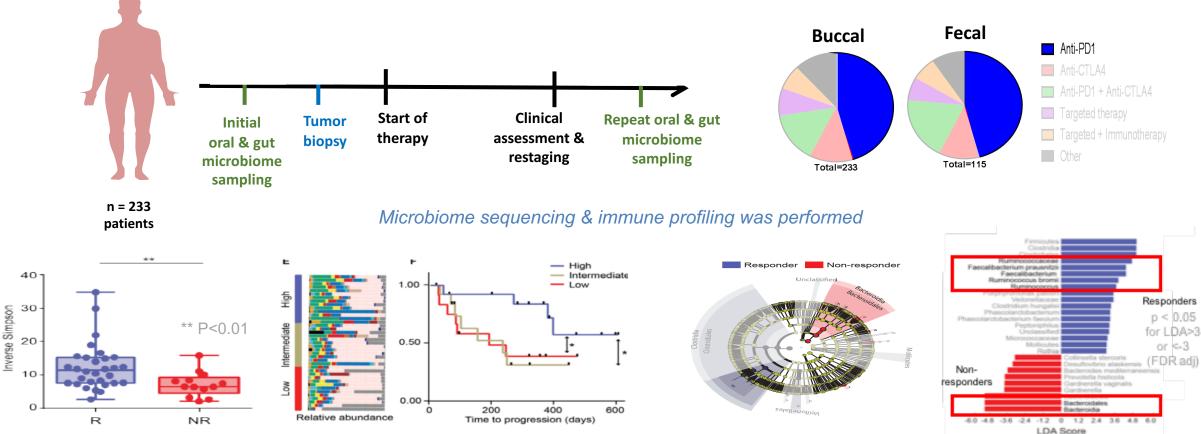
Anticancer immunotherapy by CTLA-4 blockade relies on the gut microbiota



Sivan...Gajewski Science 2015, Vetizou...Zitvogel Science 2015

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We studied oral and gut (fecal) microbiome in a large cohort of patients with metastatic melanoma going onto systemic therapy



Responders to anti-PD-1 had a higher diversity of gut bacteria associated with prolonged PFS (along with additional compositional differences)

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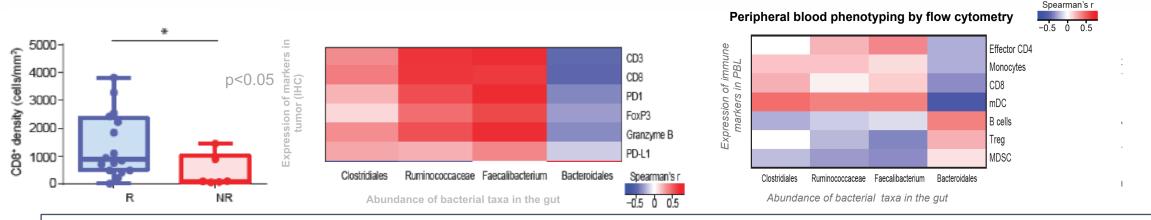
Gopalakrishnan et al, Science 2018

Deepak Gopalakrishnan PhD Christine Spencer PhD

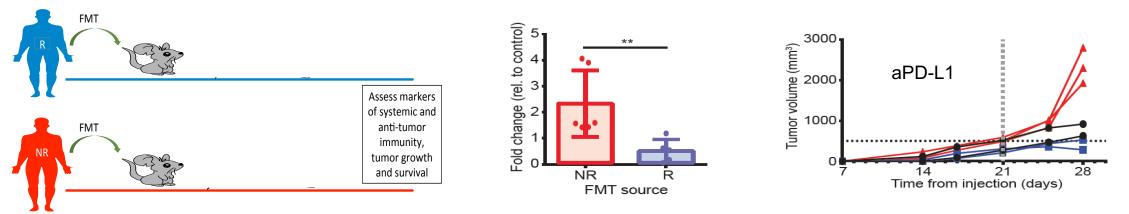


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Importantly, "favorable" signatures in the gut microbiome were associated with enhanced immune responses in the tumor microenvironment



And mechanistic studies in germ free mice showed that fecal transplant could recapitulate the phenotype



Mechanistic insights suggest that this is mediated both at the level of the gut and mesenteric lymph node, and also potentially via metabolites produced by gut microbes potentially mediating distant effects

Luigi Nezi PhD Alex Coqdill PhD ØR

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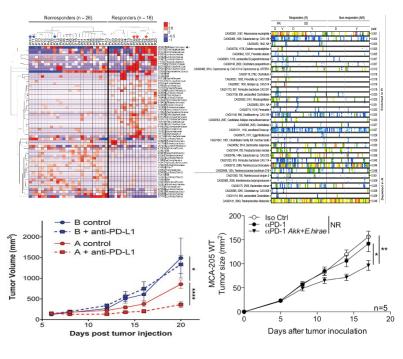
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Gopalakrishnan et al, Science 2018



Numerous studies in human cohorts now support a link between the microbiome and response (and toxicity) to cancer therapy

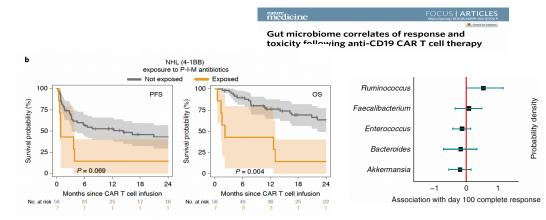
Studies in patients with melanoma, RCC, and NSCLC demonstrate differential "signatures" in R vs NR to ICB



Matson et al, Routy et al, Science 2018



Gut microbes are also strongly associated with response and toxicity to CAR-T therapy, with patients receiving antibiotics demonstrating shorter survival and higher toxicity, and specific taxa in the gut microbiome associated with prolonged survival and lower toxicity



Smith et al, Nature Medicine 2022

However, complexities exist - as taxa associated with response and lower toxicity are not congruent across all cohorts (though some unifying functional aspects exist)

mature	cine	ARTICLES https://bi.org/%01038/v41591-022-01698-3
		Check for updates

medicine MILPO//WAR/12/00

Intestinal microbiota signatures of clinical response and immune-related adverse events in melanoma patients treated with anti-PD-1 Cross-cohort gut microbiome associations with immune checkpoint inhibitor response in advanced melanoma

McCulloch et al, Nature Medicine 2022



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Can we modulate the gut microbiome to enhance responses to immunotherapy?

(and/or to abrogate toxicity)





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CLINICAL TRIALS

Fecal microbiota transplant overcomes resistance to

Joe-Marc Chauvin¹, Robert M. Morrison¹, Richelle N. Deblasio¹, Carmine Menna¹, Quanquan Ding¹,

Alicia M. Cole², Miriam R. Fernandes², Stephanie Prescott², Raquel G. F. Costa², Ascharva K. Balaii²,

anti-PD-1 therapy in melanoma patients

Diwakar Davar¹*, Amiran K. Dzutsev²*, John A. McCulloch², Richard R. Rodrigues^{2,3},

Ornella Pagliano¹, Bochra Zidi¹, Shuowen Zhang¹⁺, Jonathan H. Badger², Marie Vetizou²,

Andrey Morgun⁴, Ivan Vujkovic-Cvijin⁵, Hong Wang⁶, Amir A. Borhani⁷, Marc B. Schwartz⁸,

Howard M. Dubner⁸, Scarlett J. Ernst¹, Amy Rose¹, Yana G. Najjar¹, Yasmine Belkaid⁵,

John M. Kirkwood¹, Giorgio Trinchieri²‡§, Hassane M. Zarour^{1,9}‡§

Efforts to target gut microbes to improve response to cancer treatment are proving to be effective

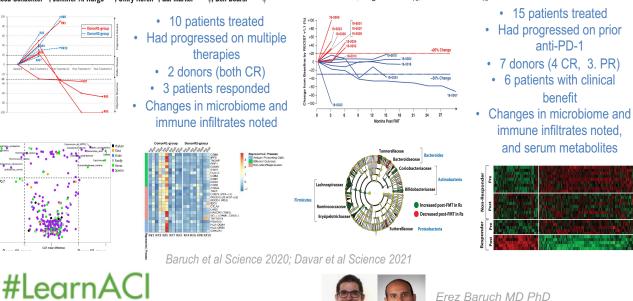
Clinical trials published in Science in 2021 demonstrate that treatment with fecal microbiota transplant (FMT) can overcome resistance to immunotherapy in patients with

metastatic melanoma

CLINICAL TRIALS

Fecal microbiota transplant promotes response in immunotherapy-refractory melanoma patients

Erez N. Baruch^{1,2}*+, Ilan Youngster^{3,4}, Guv Ben-Betzalel¹, Rona Ortenberg¹, Adi Lahat⁵, Lior Katz⁶, Katerina Adler⁷, Daniela Dick-Necula⁸, Stephen Raskin^{4,9}, Naamah Bloch¹⁰, Daniil Rotin⁸, Liat Anafi⁸, Camila Avivi⁸, Jenny Melnichenko¹, Yael Steinberg-Silman¹, Ronac Mamtani¹¹, Hagit Harati¹, Nethanel Asher¹, Ronnie Shapira-Frommer¹, Tal Brosh-Nissimov¹², Yael Eshet^{4,8,13}, Shira Ben-Simon¹⁰, Oren Ziv¹⁰, Md Abdul Wadud Khan¹⁴, Moran Amit¹⁵, Nadim J. Ajami¹⁴, Iris Barshack^{4,8}, Jacob Schachter^{1,4}, Jennifer A, Wargo^{14,16}, Omry Koren¹⁰, Gal Markel^{1,2,17}*±, Ben Boursi^{4,18,19}±



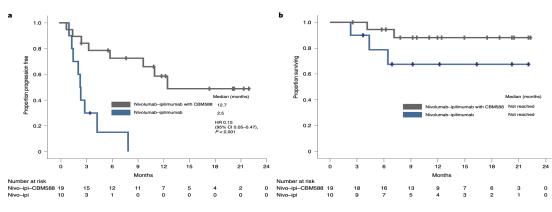
A recent clinical trial published in Nature Medicine demonstrated that treatment with a live bacterial product (CBM588) in combination with CTLA-4 and PD-1 blockade was effective in treating patients with metastatic renal cell carcinoma

medicine

OPEN

FOCUS **| ARTICLES**

Nivolumab plus ipilimumab with or without live bacterial supplementation in metastatic renal cell carcinoma: a randomized phase 1 trial



Dizman et al Nature Medicine 2022



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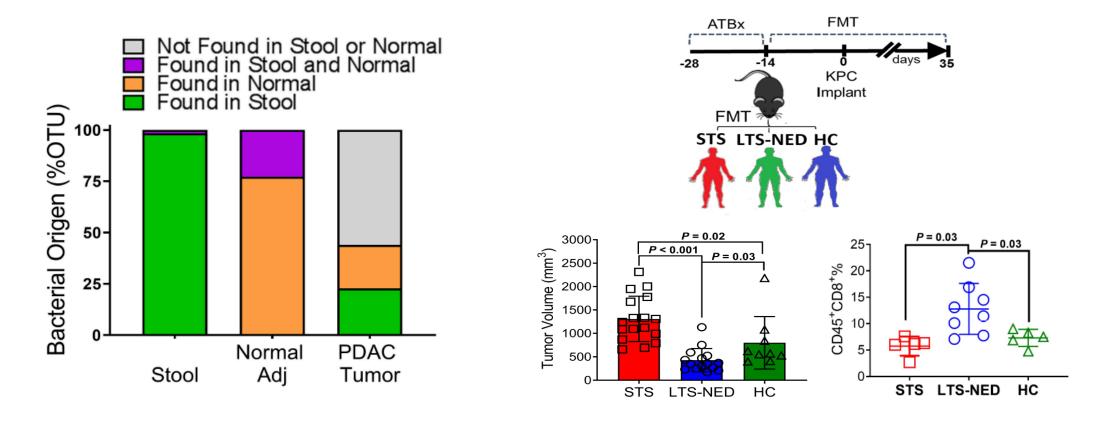
Diwakar Davar MD

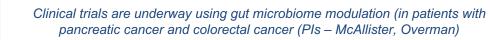
Sumanta Pal. ME

Nazli Dizman MD



There is "cross-talk" between the gut and tumor microbiome, substantiating the rationale for FMT and other microbiome modulation strategies in other cancers





Riquelme et al, Cell 2019



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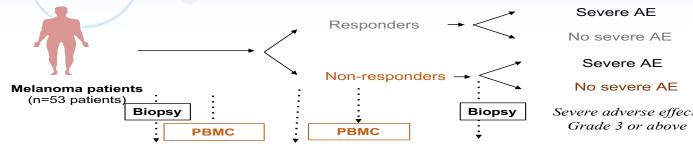
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What is the association between the gut microbiome and immunotherapy-induced autoimmunity?



We studied this in human cohorts, and identified gut microbes associated with toxicity



77% RECIST response rate

53% with > grade 3, 40% discontinued therapy

ORIGINAL ARTICLE FREE PREVIEW Microbiota as Predictor of Mortality in Allogeneic Hematopoietic-Cell Transplantation

Jonathan U. Peled, M.D., Ph.D., Antonio L.C. Gomes, Ph.D., Sean M. Devlin, Ph.D., Eric R. Littmann, B.A., Ying Taur, M.D., Anthony D. Sung, M.D., Daniela Weber, M.D., Daigo Hashimoto, M.D., Ph.D., Ann E. Slingerland, B.S., John B. Slingerland, B.S., Molly Maloy, M.S., Annelie G. Clurman, B.A., et al.

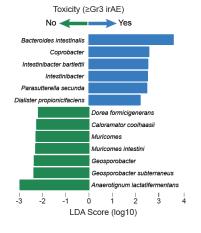
February 27, 2020

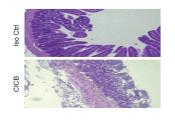
Patients with > Gr3 adverse events had a higher abundance of B. intestinalis in baseline microbiome samples, with validation in animal models (Zitvogel lab)

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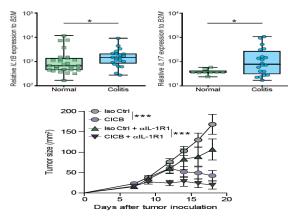
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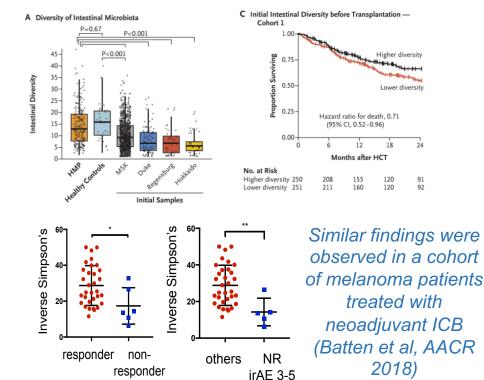
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Mechanistically, this appears to be mediated via IL-1B and IL-17, and treatment with IL-1B blockade abrogates toxicity without impairing response



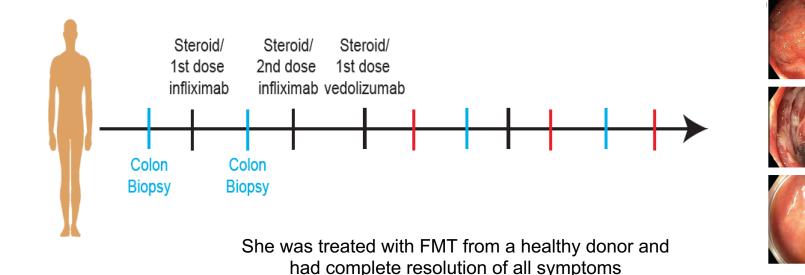


Andrews et al Nature Medicine 2021

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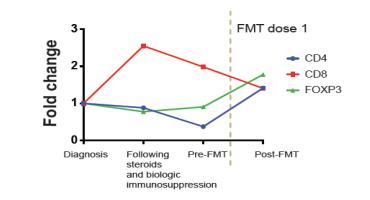


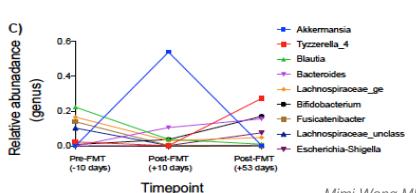
Gut microbiome modulation may also be helpful in treating immunotherapy toxicity



50 yo female with metastatic urothelial cancer was treated with aCTLA-4 + a PD-1 and developed colitis refra

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Diagnosis

Following 3 immunosuppr agents

Post-FMT

CD4

CD

FOXP3

Mimi Wang MD PhE Rob Jeng MD

Pre-FMT

Post-1 dose FMT



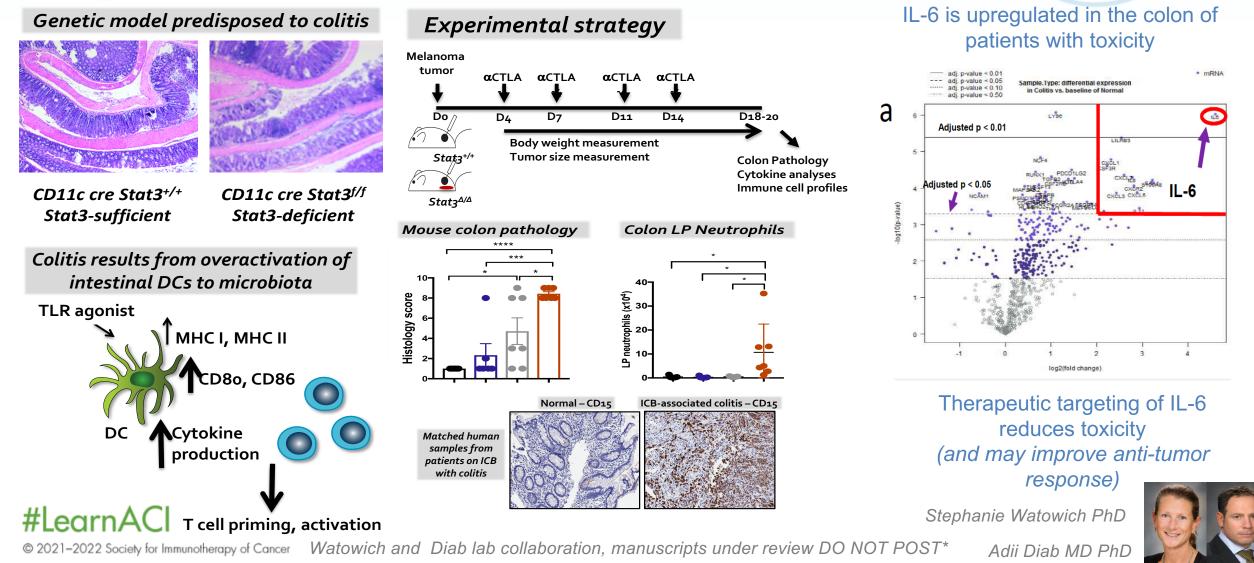
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Wang et al, Nature Medicine 2018

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We are working with others to generate better pre-clinical models of toxicity and to better understand how to target this (via gut microbiome modulation and other strategies)





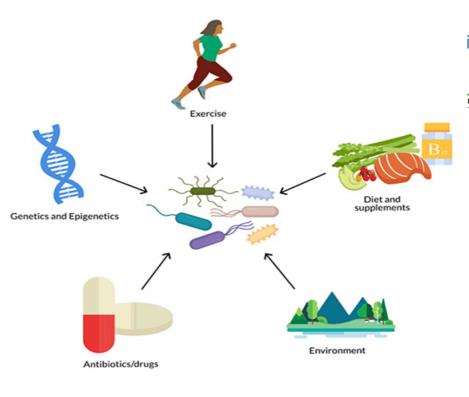
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Given the critical role of the gut microbiome, what is the role of diet (and other factors) in response to cancer treatment?

You are what you eat!

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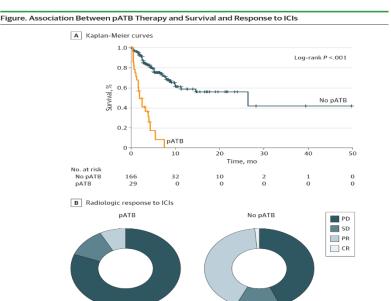
Microbes in the gut are influenced by a number of features including diet, antibiotics, and environmental factors



Hughes Frontiers in Nutrition 2020

Numerous studies have shown that patients receiving antibiotics before treatment with immune checkpoint blockade (ICB) have worse outcomes (response and survival)

However, some targeted antibiotic approaches may actually enhance response to ICB



0 50 100 150 200 Months

.....

Survival Proportions with Anti-CTLA-4

Probability of Surviv

50

Stephanie Watowich PhD Liz Park PhD Vivek Subbiah MD

Targeted antibiotic

Broad spectrum antibiotics

No antibiotics

Pinato et al, JAMA Oncology 2019

These results have potential implications for patients with earlier stage disease, and implications far beyond cancer

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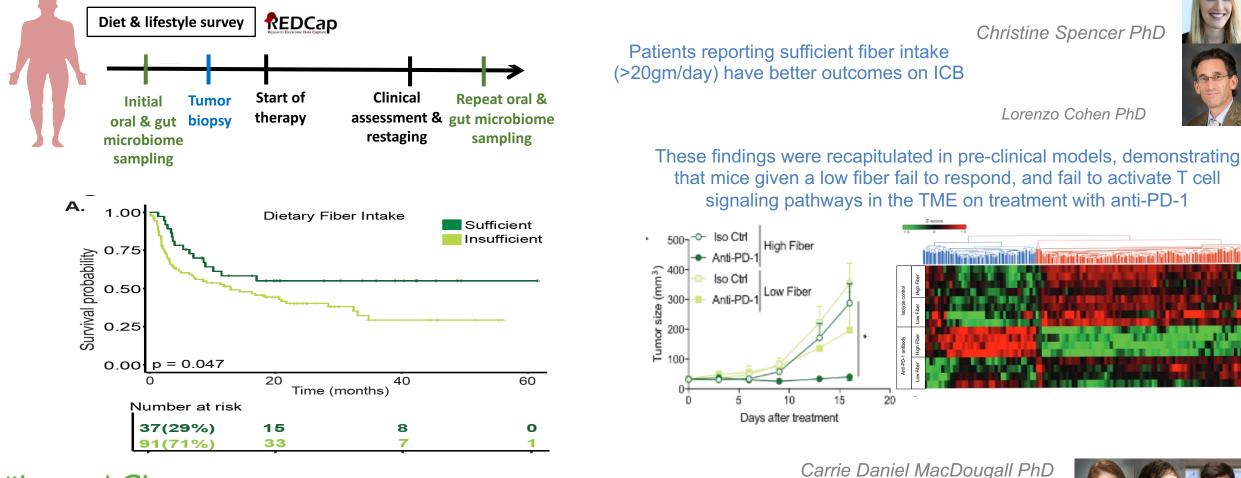
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In our cohort, we also studied the influence of diet and lifestyle factors on the microbiome and response to immune checkpoint blockade



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Spencer et al, Science 2021

Jen McQuade MD

Giorgio Trinchieri PhD

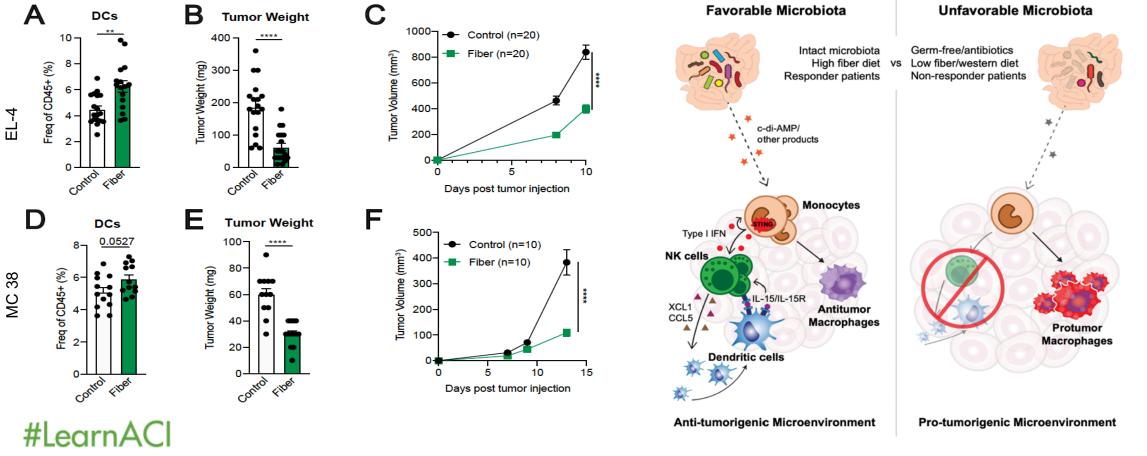
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This data is galvanized by data from others that high dietary fiber intake promotes anti-tumor immunity

Mice treated with a high fiber diet have delayed tumor outgrowth and more DCs

Gut microbiota and dietary fiber shape the TME in part via monocyte reprogramming by STING-mediated IFN signaling

Romina Goldszmid, PhD



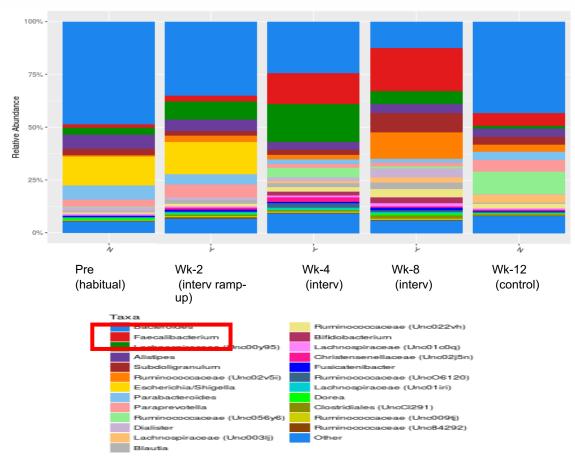
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Lam et al, Cell 2021

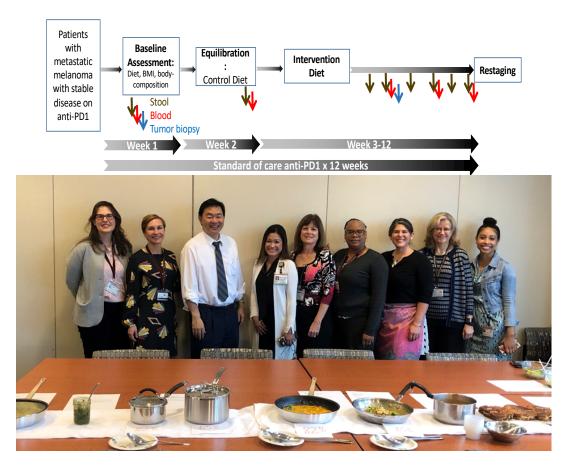


There is evidence that changes in diet can have an impact on gut microbes and associated physiology in a short time frame



Daniel et al, confidential unpublished data DO NOT POST

We are now running dietary intervention trials in combination with checkpoint blockade (funded by Seerave and other foundations) *Carrie Daniel, Jen McQuade, et al*



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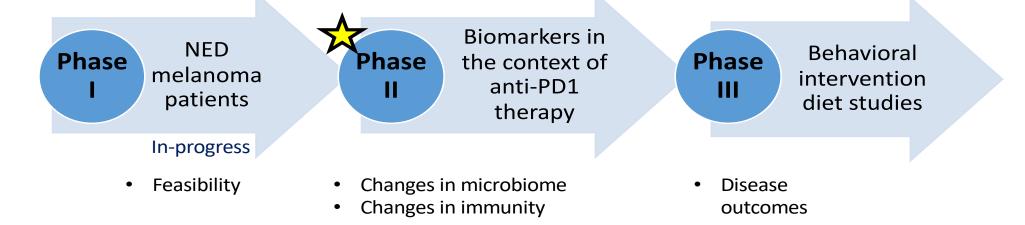
Testing diet as a precision intervention in cancer:

Hypothesis:

A whole foods-based, fiber-rich diet will modulate the microbiome and enhance systemic and anti-tumor immunity



Carrie Daniel PhD MPH and Jen McQuade MD



DIET (Diet and Immune Effects Trial):

All calorie-containing food and beverages prepared and provided to patients

SEERAVE FOUNDATION Research Alliance Research Alliance Research Alliance Research Alliance Research Alliance Research Re





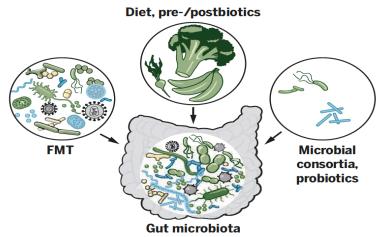
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Strategies to alter gut microbiota to improve responses (and to reduce toxicity) are currently underway, but numerous considerations exist as we use these approaches

Strategies to alter gut microbiota

Fecal microbiota transplant (FMT) involves transfer of fecal microbiota from a donor to another individual. Alternatively, microbial consortia (targeted formulations used to augment host microbiota) are being developed. Diet, prebiotics, and postbiotics can also influence the microbial community.



Prior to treatment	During therapy	Assessing impact	Long-term effects	
Patients - What patient population to treat? Treatment naïve or refractory? - Should the microbiome be profiled to stratify / select patients? Pre-conditioning regimen - Do we need to pre-treat the subwith estiblication to pre-treat	What therapy should we combine with modulation of the gut microbiome? - Immune checkpoint blockade (anti-PD-1)? - Other forms of immunotherapy? Adapte - Other therapy?	What are appropriate primary endpoints for such studies? - Safety and tolerability - Engraftment - Others? d from McQuade et al, Lancet Oncology	 Durability of engraftment How durable is engraftment? What microbes / functional phenotypes in gut microbiota are associated with responses? And can these be 	
the gut with antibiotics to facilitate engraftment? How should we optimally modulate the gut microbiota? - FMT? - How should FMT be administered? - How do we select donors? - Should patient fecal material be "banked" for later auto-FMT? - Diet, Designer Consortia? - Phage / antibiotics / other?	 How do we optimally monitor patients during therapy? Microbiome analyses to assess engrafment / function? Immune profiling? Peripheral blood Tumor How can we facilitate stable engraftment? Should we recommend dietary changes? Any medications to avoid? 	What are appropriate secondary endpoints? - Response / Toxicity? - Radiographic (RECIST and / or irRC) - Rate of complete responses - Pathologic response (on biopsy or after neoadjuvant therapy) - Novel markers (ctDNA, immunophenotyping)	Overall responses - What is impact on overall and disease-specific survival? Toxicity - Can we uncouple toxicity and response to immunotherapy? Other transplanted traits with FMT? - Obesity? - Depression? - Any potentially favorable traits?	

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James Strommer

ERY

Ancient times

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-present

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<u>Could microbiome targeting become the next "pillar" of cancer care?</u>

th strategies to monitor and modulate the microbic personalized nutrition



Gut health could be an important piece in the Covid-19 puzzle

Markham Heid Feb 3 · 7 min read *

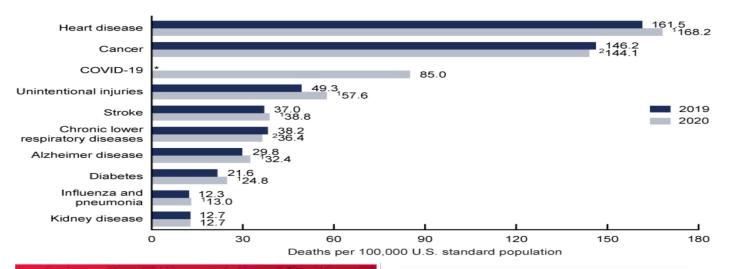
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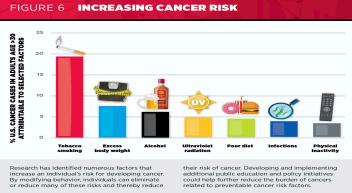
DISCOVER BREATH BIOPSY

From AACR Cancer Progress Report

Sitc Advances in Cancer Immunotherapy™

These same factors are influencing other diseases, and we can work together to make changes to promote overall health





erican Association for Cancer Research (AACR) Cancer Progress Report 2020

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Society for Immunotherapy of Cancer

Bolte et al, Gut 2021

Can we monitor and modulate gut microbes, diet, and other variables in cancer treatment, and to promote overall health?



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We can help address these issues on a global scale and also as individuals



The choices that we make every day have a tremendous impact on our microbiome and on our physiology - and also on our planet



Advances in Cancer Immunotherapy™

Conclusions and potential implications of these findings:

- We have made significant progress in the treatment of melanoma and other cancers with the use of immunotherapy, however not all patients respond - and toxicity remains a major issue
- A deep understanding of the numerous factors that contribute to therapeutic response and toxicity are needed (including factors internal and external to the host such as the microbiome)
- Multidisciplinary teams (involving patients, families, clinicians, basic & translational researchers, foundations / funding bodies, pharma) are all key in advancing the field, and we can learn a lot from each other to push the field forward faster
- There is still a great deal to learn, but the future is bright



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Patients and their families

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