## Impact of COVID-19 on oncology clinical <u>trials</u> *Nature Reviews Drug Discovery*, May 18, 2020

Samik Upadhaya, Jia Xin Yu, Cristina Oliva, Megan Hooton, Jeffrey Hodge & Vanessa M. Hubbard-Lucey



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org



Proportion of surveyed institutions continuing to enrol new patients into ongoing cancer clinical trials



Impact on patient enrolment in active oncology clinical trials, based on survey responses from 22 investigators leading trials in the United States (10), Europe (7) and Asia (5).

Upadhaya et al. Nature Reviews Drug Discovery. May 2020



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org

Trial considerations causing the most difficulty for enrolment in active trials





Factors affecting enrolment for ongoing trials highlighted by 13 investigators, who selected their top three considerations. Percentages reflect responses within each category out of the total of 39 responses

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Contact: CRI Clinical Accelerator accelerator@cancerresearch.org

#### Key considerations for upcoming trials





Key considerations for future trials highlighted by 22 investigators. Percentages reflect responses within each category out of the total of 52 responses.

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Contact: CRI Clinical Accelerator accelerator@cancerresearch.org

#### Impact on delayed or cancelled visits for cancer patients in trials



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### Focus of discussions with IRB/IEC





Topics discussed with an institutional review board (IRB) or independent ethics committee (IEC). Percentages are out of the total of 30 responses from 11 investigators

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Telemedicine -		8	32						18	-
ternative location for	73								27	
Avoiding immuno-		73							27	
Reduced site visits		73							27	-
Remote EMR –		73							27	-
Shipping oral drugs -		64							36	
Virtual site visits –		59							41	-
Deferring chemo or –	50								50	
0	10	20	30	40	50	60	70	80	90	100
Status		Per	rcenta	ge of	survey	/ respo	onses	(%)		

#### Technologies/strategies being considered for clinical trial assessments



Comparison of institutional strategies for clinical trial assessments and quality monitoring as a result of COVID-19. Percentage of respondents aware of current or future implementation and unaware of such measures at their institution are shown, based on 198 responses from 22 investigators.

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Contact: CRI Clinical Accelerator accelerator@cancerresearch.org





Operational risks, based on an analysis conducted by IQVIA of a subset of its oncology trials (n > 200).

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Contact: CRI Clinical Accelerator accelerator@cancerresearch.org



#### Oncology trials suspended owing to COVID-19



Number of interventional oncology trials suspended in March and April owing to COVID-19. Data extracted from ClinicalTrials.gov on 12 May 2020. 'Other' includes phase IV trials and trials for which the phase is not stated.

Upadhaya et al. Nature Reviews Drug Discovery. May 2020



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org

# <u>Cancer cell therapies: the clinical trial</u> <u>landscape</u> *Nature Reviews Drug Discovery*, May 26, 2020

Jia Xin Yu, Samik Upadhaya, Revati Tatake, Fern Barkalow & Vanessa M. Hubbard-Lucey



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org





**Trends in the cancer cell therapy pipeline.** Comparison of the pipeline in March 2019 and March 2020 (data on analysis included in the Supplementary file). TAA, tumour-associated antigen; TCR, T cell receptor; TIL, tumour-infiltrating lymphocyte; TSA, tumour-specific antigen.

Yu et al. Nature Reviews Drug Discovery. May 2020.



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org

The Anna-Maria Kellen

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Comparison of endpoint status of trials with published results by cancer types, therapy types, and phases. (Positive = Fully/Partially Achieved Endpoints, Negative = Did not achieve endpoints)

Yu et al. Nature Reviews Drug Discovery. May 2020.



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org





Contact: CRI Clinical Accelerator accelerator@cancerresearch.org



The Anna-Maria Kellen **Clinical Accelerator** Landscape of cance pipeline from 2020 u development stage. Landscape of cancer cellular immunotherapy pipeline from 2020 update by country of origin and

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Number of All Cell Immunotherapy Clinical Trials



Landscape of all cancer cellular immunotherapy trials extracted from GlobalData's clinical trials database (data cut off March 31, 2020) based on trial phase and therapy type.

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Contact: CRI Clinical Accelerator accelerator@cancerresearch.org



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Contact: CRI Clinical Accelerator accelerator@cancerresearch.org





Contact: CRI Clinical Accelerator accelerator@cancerresearch.org





Contact: CRI Clinical Accelerator accelerator@cancerresearch.org





Comparison of all cancer cellular immunotherapy clinical trials by main country and therapy types with data cutoff date March 31, 2020.

Yu et al. Nature Reviews Drug Discovery. May 2020.



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org

Immuno-oncology drug development forges on despite COVID-19 Nature Reviews Drug Discovery, September 18, 2020 Samik Upadhaya, Vanessa M. Hubbard-Lucey & Jia Xin Yu



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org



Trends in the immuno-oncology (IO) drug development pipeline The 4,720 IO agents in the current global clinical pipeline are compared with the pipelines from analogous analyses in previous years, based on the therapy type.

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Contact: CRI Clinical Accelerator accelerator@cancerresearch.org





Top immuno-oncology targets for active and deprioritized agents in the drug development pipeline from 2019 and 2020. We consider inactive agents those that are not actively investigated owing to lack of efficacy, safety, or for business development reasons.

Upadhaya et al. Nature Reviews Drug Discovery. September 2020.



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Contact: CRI Clinical Accelerator accelerator@cancerresearch.org



Target cell landscape of immunomodulators and CD3-targeted bispecific monoclonal antibodies over the past 3 years. "Immune cells" indicates broad immune cell targets. TIL=tumor infiltrating lymphocytes, TME= tumor microenvironment, DC = dendritic cells, NK= natural killer cells, Immune cells = several different immune cell types

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Contact: CRI Clinical Accelerator accelerator@cancerresearch.org

The Anna-Maria Kellen

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Start date of IO trials per year indicates a dip in new trials started towards the end of 2019, with recovery in summer 2020 to continue the lower but upward trend of new trials.

Upadhaya et al. Nature Reviews Drug Discovery. September 2020.



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org

<u>Combinations take centre stage in</u> <u>PD1/PDL1 inhibitor clinical trials</u> *Nature Reviews Drug Discovery*, November 11, 2020

Samik Upadhaya, Svetoslav T. Neftelino, Jeffrey P. Hodge, Cristina Oliva, Jay R. Campbell & Jia Xin Yu



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org





The Anna-Maria Kellen Clinical Accelerator

The landscape of anti-PD1/PDL1 mAb clinical trials in 2017 and 2020. As of September 2020, 4,400 clinical trials are in the current landscape, nearly tripling since in September 2017. Other PDx includes any anti-PD1/L1 mAbs without FDA approvals.

Upadhaya et al. Nature Reviews Drug Discovery. November 2020.



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org





Comparison of monotherapy and combination trials. The majority of new trials since 2014 have been combination trials (bar graphs). The average planned patient enrolment (line graph) has decreased since 2014 for monotherapy trials more than for combination trials. \*Only data from the first three guarters of 2020 were used to generate the analysis.

Upadhaya et al. Nature Reviews Drug Discovery. November 2020.



Contact: CRI Clinical Accelerator accelerator@cancerresearch.org



![](_page_29_Picture_1.jpeg)

**Main targets assessed in combination with anti-PD1/L1 mAbs.** The graph shows the number of combination trials starting each year since 2011. The main 20 targets assessed in combination are shown in descending order according to the number of trials started in 2020. \*Only data from the first three quarters of 2020 were used to generate the analysis.

Upadhaya et al. Nature Reviews Drug Discovery. November 2020.

![](_page_29_Picture_4.jpeg)

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![](_page_30_Figure_0.jpeg)

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Growth of landscape of PD1/L1 mAb clinical trials from 2017 to 2020. 4,400 clinical trials are in the current landscape as of September 2020, nearly tripling since in September 2017. FDA-approved mAbs include pembrolizumab, nivolumab, durvalumab, atezolizumab, avelumab, and cemiplimab. Other PDx include mAbs approved by regulatory agencies other than the FDA such as the EMA as well as those in clinical development and not yet approved.

Upadhaya et al. Nature Reviews Drug Discovery. November 2020.

![](_page_30_Picture_4.jpeg)

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![](_page_31_Figure_0.jpeg)

![](_page_31_Picture_1.jpeg)

Anti-PD1/L1 monotherapy and combination trials started from 2014 to 2020 (\*Only data from the first 3 quarters of 2020 were used to generate the analysis in the chart above.)
The majority of trials started in last 4 years remain in recruitment phase, where the most recent trials have not started recruitment.

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![](_page_31_Picture_4.jpeg)

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![](_page_32_Figure_0.jpeg)

![](_page_32_Picture_1.jpeg)

The median patient recruitment rate in different countries or regions in 2019 compared to 2020 with the percent change between the years. Six major markets are France, Germany, Italy, Japan, Spain and United Kingdom. The Asia-Pacific (APAC) area includes Australia, Hong Kong, Korea, New Zealand, Taiwan, and Thailand, while excluding China and Japan. Mono and Combo denote monotherapy and combination therapy trials respectively.

Upadhaya et al. Nature Reviews Drug Discovery. November 2020.

![](_page_32_Picture_4.jpeg)

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![](_page_33_Figure_0.jpeg)

![](_page_33_Picture_1.jpeg)

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Target landscapes of combination trials in 2020 and 2017. The number of combination trials has more than tripled in the past three years (2,900 compared to 857), with an increase of 129 additional combination target groups from 124 target groups. Similar targets are grouped together to better identify trends in year-to-year analyses.

Upadhaya et al. Nature Reviews Drug Discovery. November 2020.

![](_page_33_Picture_4.jpeg)

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![](_page_34_Figure_0.jpeg)

![](_page_34_Picture_1.jpeg)

Analysis of new combination trials (724 trials) starting in the year 2020\* (\*Only first 3 quarters of 2020 are included in the analysis.)

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![](_page_34_Picture_4.jpeg)

Contact: CRI Clinical Accelerator accelerator@cancerresearch.org