# 2021 SNMMI Highlights Lecture: Oncology and Therapy, Part 1

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*From the Newsline Editor: The Highlights Lecture, presented at the closing session of each SNMMI Annual Meeting, was originated and presented for more than 30 years by Henry N. Wagner, Jr., MD. Beginning in 2010, the duties of summarizing selected significant presentations at the meeting were divided annually among 4 distinguished nuclear and molecular medicine subject matter experts. Each year Newsline publishes these lectures and selected images. The 2021 Highlights Lectures were delivered on June 15 as part of the SNMMI Virtual Annual Meeting. In this issue we feature the first part of the lecture by Heiko Schöder, MD, MBA, chief of the Molecular Imaging and Therapy Service at Memorial Sloan Kettering Cancer Center (New York, NY) and a professor of radiology at the Weill Medical College of Cornell University (New York, NY), who spoke on oncology and therapy highlights from the meeting. The second part of the lecture will appear in the November issue of Newsline. Note that in the following presentation summary, numerals in brackets represent abstract numbers as published in* The Journal of Nuclear Medicine *(2021;62[suppl 1]).*

First I would like to thank the organizers for inviting me to give this year's highlights lecture on oncology and therapy. It is a pleasure to present these findings. We will begin with a brief statistical characterization of the oncology-related abstracts presented at the 2021 SNMMI Annual Meeting. The majority (51%) came from North America, with a second large percentage of contributions from Asia (41%), and others from Europe (6%), Africa (1%), and South America (1%). Among international countries contributing, a large number of abstracts came from China (166), followed by Korea (61), Japan (57), India (34), Canada (34), and Australia (20). As in past years, the majority (80%) of these abstracts focused on diagnostics, with only about 20% on therapeutic applications.

Among the highest rated abstracts in the clinical area, many were focused on fibroblast activation protein inhibitor (FAPI) and prostate-specific membrane antigen (PSMA) imaging in one form or another, and these will be discussed in detail in this lecture. In the area of basic research, no clear topic emerged as dominant. A number of new probes were presented at the meeting, and we will look at several of these. In the area of therapy, the large majority of abstracts focused on prostate cancer and neuroendocrine tumors.

## Clinical Diagnostics

### *FAPI*

Many of us remember the 2019 SNMMI Image of the Year (Fig. 1) from multiple researchers at the University Hospital Heidelberg (Germany), which showed FAPI uptake across a wide range of malignancies (*1*). In the intervening 2 years, numerous case reports and small clinical studies have shown the utility of FAPI-based imaging in diagnosis, staging, radiation therapy planning, and changes in patient management across a range of malignant diseases and sites, including (among others) the lung, pancreas, lower gastrointestinal tract, and head and neck and in sarcoma and peritoneal carcinomatosis. Results from these and other studies, however, have also shown that FAPI is not a cancer-specific agent. Uptake has been shown in a range of inflammatory conditions, including thyroiditis, benign pancreatic lesions, pulmonary fibrosis, solitary fibrous tumor, and others, as well as in the postmyocardial infarction setting.

**Heiko Schöder, MD**

As background, the tumor microenvironment includes blood vessels, extracellular matrix, and a number of different types of cells, including cancer-associated fibroblasts (CAFs). CAFs are relevant in cancer progression, resistance to therapy, and also in regulating the immune environment. They can be targeted by a number of therapies. FAP is a transmembrane glycoprotein and prognostic marker in cancer expressed only on activated fibroblasts, including activated CAFs. FAP can be targeted in a variety of ways, including by FAPIs, which we use for imaging. As noted, a number of smaller studies have been published, and the field is ready to move on to larger and more quantitative analyses to study the role of FAPI in selected malignancies.

Kessler et al. from the University of Duisberg-Essen, the German Cancer Consortium (DKTK, Essen; DKFZ, Heidelberg), and University Hospital Essen (all in Germany) reported on "$^{68}$Ga-FAPI for sarcoma imaging: Data from the FAPI-PET prospective observational trial" [126]. The study included 47 patients with bone and soft tissue sarcoma who underwent clinical $^{68}$LGa-FAPI PET imaging, 46 of whom also underwent $^{18}$F-FDG PET. The study's primary endpoint was association of $^{68}$Ga-FAPI PET uptake intensity and histopathologic FAP expression. Secondary endpoints were detection rate, positive predictive value (PPV), interrater reproducibility, and change in management. The $^{68}$Ga-FAPI tracer showed high sensitivity and PPV on a per patient and per region basis. In a comparison of detected rates, $^{68}$Ga-FAPI PET results were similar to those with $^{18}$F-FDG PET, although in some instances $^{18}$F-FDG provided additional

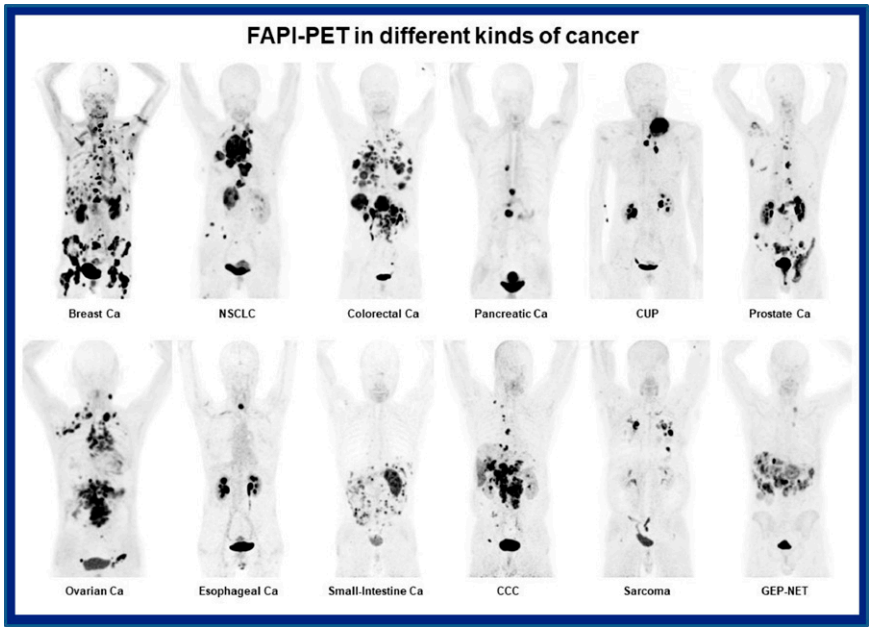


**FIGURE 1.** SNMMI 2019 Image of the Year: $^{68}$Ga-FAPI PET/CT in patients reflecting 12 different tumor entities. Ca = cancer; NSCLC = non–small cell lung cancer; CUP = carcinoma of unknown primary; CCC = cholangiocarcinoma; GEP-NET = gastroenteropancreatic neuroendocrine tumor. Image was created with contributions from Clemens Kratochwil, Paul Flechsig, Thomas Lindner, Labidi Abderrahim, Annette Altmann, Walter Mier, Sebastian Adeberg, Hendrik Rathke, Manuel Rohrich, Hauke Winter, Peter Plinkert, Frederik Marme, Matthias Lang, Hans Ulrich Kauczor, Dirk Jaeger, Juergen Debus, Uwe Haberkorn, and Frederik L. Giesel, each of whom was affiliated with University Hospital Heidelberg (Germany).

information. It is possible that in the future, at least in some patients, complete workups may require both radiotracers. The authors found that the $^{68}$Ga-FAPI tracer uptake correlated with immunohistochemistry (IHC)-assessed FAP expression in sarcoma: the higher the FAP expression on IHC, the higher the SUV. Figure 2 is an example from 2 patients, 1 with negative IHC FAP and no uptake on imaging, 1 with positive IHC FAP and high uptake on imaging.

Mona et al. from the University of California Los Angeles/University of California Los Angeles Medical Center reported on "Validation of FAPi PET biodistribution by immunohistochemistry in patients with solid cancers: A prospective exploratory imaging study" [1000]. This study included 15 patients and a variety of tumors and looked at similar correlations, using tissue microarrays to explore whether $^{68}$Ga-FAPi-46 PET image biodistribution accurately reflects FAP expression from resected tumor and nontumor specimens. Figure 3 is an interesting patient example, showing strong uptake in a pancreatic tail ductal adenocarcinoma with the corresponding IHC stain. FAP IHC in representative histologic sections demonstrated variable negative-to-weak FAP expression in normal pancreatic parenchyma, except for a subpopulation of cells in normal islets consistently showing strong FAP expression. Again, we see a direct relationship between IHC in tissue and SUV on FAPI PET. The researchers concluded that this and associated translational validation "pave the way for large-scale prospective trials on the use of $^{68}$Ga-FAPi-46 PET/CT as a biomarker and stratification tool for FAP-targeted therapies."

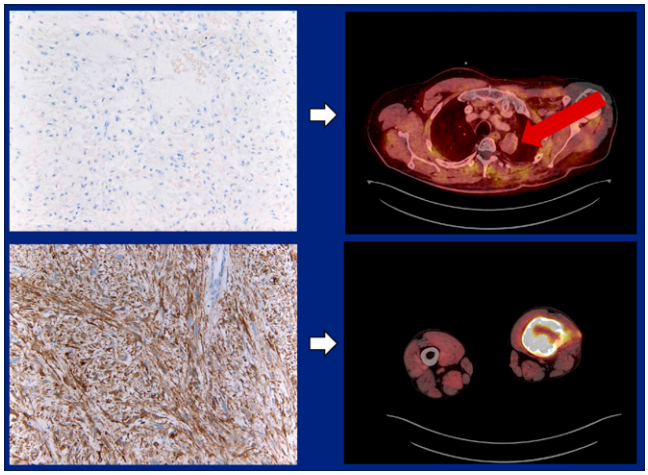

**FIGURE 2.** $^{68}$Ga-FAPI for sarcoma imaging. Data from the FAPI-PET prospective observational trial [126]. Immunochemistry (IHC)-assessed FAP expression in sarcoma correlated well with $^{68}$Ga-FAPI tracer uptake. Top: IHC (left) and FAPI PET/CT (right) images in a patient with FAP– disease. Bottom: corresponding images in a patient with FAP+ disease.

Other abstracts on FAPI imaging were presented at this meeting, and time does not allow me to detail each of these, but several have already been published in major journals. Chen et al. from First Affiliated Hospital of Xiamen University/Xiamen University (China) reported on the "Role of $^{68}$Ga-FAPI PET/CT in the evaluation of peritoneal carcinomatosis and comparison with $^{18}$F-FDG PET/CT" [20] (*2*). This is a challenging indication in PET and PET/CT imaging. The retrospective study included 46 patients (16 with diffuse-type peritoneal carcinomatosis, 27 with nodular-type peritoneal carcinomatosis, and 3 true-negative patients). The researchers presented encouraging data indicating that FAPI uptake was higher than that of $^{18}$F-FDG, that FAPI PET allowed detection of smaller lesions, and that a particular

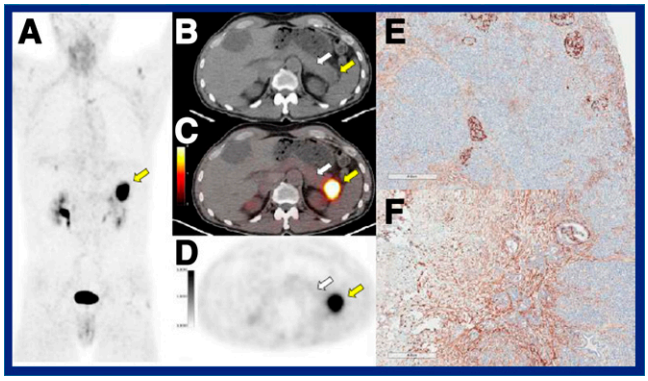


**FIGURE 3.** Validation of FAPi PET biodistribution by immunohistochemistry (IHC) in patients with solid cancers. Example: 65-year-old man with pancreatic ductal adenocarcinoma (yellow arrows: pancreatic tail ductal adenocarcinoma lesion; white arrows: resected normal pancreas region). (A) Whole-body PET; (B) transaxial CT; (C) transaxial PET/CT ($SUV_{max}$ 15.69); (D) transaxial PET ($SUV_{mean}$ 12.51). (E) FAP IHC on representative histologic sections demonstrated variable negative-to-weak FAP expression in normal pancreatic parenchyma with a subpopulation of cells in normal islets consistently showing strong FAP expression; and (F) moderate-to-strong FAP expression was noted for tumor tissue.

advantage for FAPI PET was evident in gastric and colon cancers.

Pang et al. from Xiamen University/First Affiliated Hospital of Xiamen (China) reported on "Comparison of $^{68}$Ga-FAPI and $^{18}$F-FDG uptake in gastric, duodenal, and colorectal cancers" [125] (*3*). They reported that $^{68}$Ga-FAPI PET/CT was superior to $^{18}$F-FDG PET/CT in detection of primary and metastatic lesions, with higher tracer uptake in most primary and metastatic lesions.

Other related abstracts looked at nasopharyngeal cancer, where FAPI imaging provided additional advantages in evaluating skull base invasion, suggesting that FAPI PET/MR may become routine in future evaluations in this setting. Qin et al. from Union Hospital, Tongji Medical College, and Huazhong University of Science and Technology (Wuhan, China) reported on "A head-to-head comparison of $^{68}$Ga-DOTA-FAPI-04 and $^{18}$F-FDG PET/MR in patients with nasopharyngeal carcinoma: A prospective study" [124] (*4*). They found that $^{68}$Ga-FAPI outperformed $^{18}$F-FDG in delineating primary tumors and detecting distant metastases, particularly in the evaluation of skull-base and intracranial invasion, concluding that "$^{68}$Ga-FAPI hybrid PET/MR has the potential to serve as a single-step staging modality" for patients with nasopharyngeal cancer. Zhao et al. from the First Affiliated Hospital of Xiamen University (China) reported on the "Clinical utility of $^{68}$Ga-FAPI PET/CT for primary staging and recurrence detection in nasopharyngeal carcinoma" [1086] (*5*) in a study with 45 participants. Their data also indicated higher uptake of $^{68}$Ga-FAPI than $^{18}$F-FDG.

### *Prostate Cancer*

Prostate cancer remains a significant burden across the globe, including the Americas, large portions of Africa and Europe, and Australia. On May 12, a new Lancet Commission was announced to study prostate cancer in greater detail, to create recommendations for prostate cancer diagnosis and treatment, and to address disparities in prostate cancer management. The announcement noted that "genomic tools and imaging, particularly PSMA PET-CT, are likely to be increasingly important in treatment decisions in the future" (*6*).

Two large and influential recent studies have focused on prostate cancer, 1 on $^{68}$Ga-PSMA-11 and the other on $^{18}$F-DCFPyL. Fendler from the University of California at Los Angeles and an international consortium of research centers reported in *JAMA Oncology* on an "Assessment of $^{68}$Ga-PSMA-11 PET accuracy in localizing recurrent prostate cancer: A prospective single-arm clinical trial" (*7*). The study included 635 men with biochemically recurrent prostate cancer after treatment and identified high PPV, high detection rate, and high interreader agreement for localization with $^{68}$Ga-PSMA-11 PET. Morris et al. from Memorial Sloan Kettering Cancer Center (New York, NY) and an international consortium of research centers reported in *Clinical Cancer Research* on "Diagnostic performance of $^{18}$F-DCFPyL-PET/CT in men with biochemically recurrent prostate cancer: Results from the CONDOR phase III, multicenter study" (*8*). The study included 208 men with rising prostate-specific antigen (PSA) ≥0.2 ng/mL after prostatectomy or ≥2 ng/mL above nadir after radiotherapy. Of note, patients were included in the $^{68}$Ga-PSMA-11 study irrespective of prior imaging findings, whereas in the $^{18}$F-DCFPyL study, the median PSA was lower and only patients with negative or equivocal prior imaging were enrolled. Nevertheless, we can identify common themes in their findings: higher overall detection rates (75% for $^{68}$Ga-PSMA-11; 59%–66% with $^{18}$F-DCFPyL) correlated with increasing PSA levels and very respectable numbers in terms of PPV and sensitivity (sensitivity here referring to cases with histologic verification). Reader agreement results were also good with both tracers.

Rowe from Johns Hopkins Medicine (Baltimore, MD) and the CONDOR consortium provided additional data from their study at this meeting in "A phase 3 study of $^{18}$F-DCFPyL PET/CT in patients with biochemically recurrent prostate cancer (CONDOR): An analysis of disease detection rate and PPV by anatomic region" [123]. They found that $^{18}$F-DCFPyL PET/CT detected and localized metastatic lesions with high PPV regardless of anatomic region (prostate/prostate bed, pelvic lymph nodes, or extrapelvic regions, including lymph nodes, bone, and viscera/soft tissue) (Fig. 4). Higher PPVs were observed in extrapelvic lymph nodes and bone compared to viscera/soft tissue. This is, of course, important, because an imaging agent may not be very useful if it addresses disease only in the pelvis but not outside (or vice versa). I should point out that the number of visceral lesions in this study was quite small, so related data probably should not be overinterpreted.

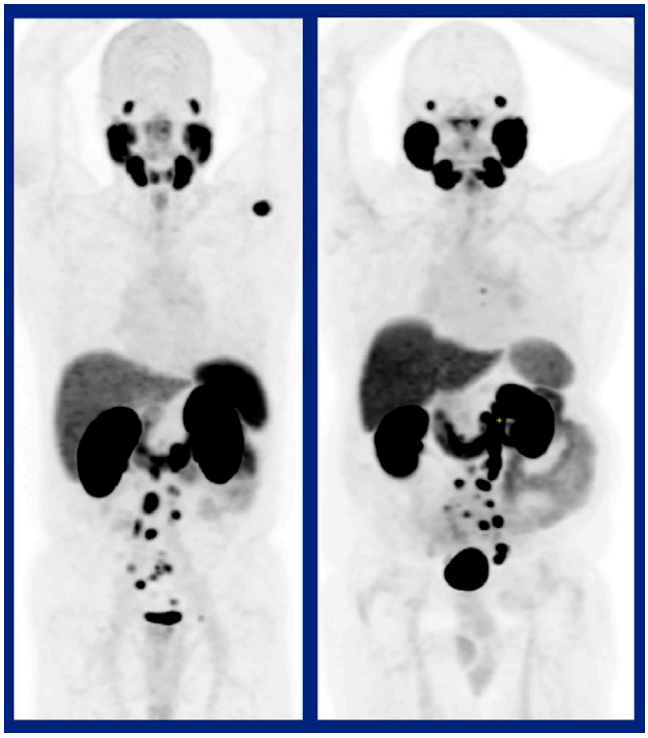

**FIGURE 4.** Left: Representative imaging from the $^{68}$Ga-PSMA-11 PET/CT trial from UCLA and an international consortium. Right: Representative imaging from the CONDOR phase III $^{18}$F-DCFPyL PET/CT trial. Despite difference in enrollment criteria and procedures, common findings included higher overall detection rates that correlated with increasing prostate-specific antigen levels, good positive-predictive values, and improved sensitivity. Reader agreement results were also high with both tracers.

Other abstracts were presented on these and other PSMA compounds. Although I cannot detail each one, I want to highlight 4 as illustrative of current research and findings. Lin et al. from the University of California at San Francisco reported on "The increased prevalence of low and heterogeneous PSMA uptake in the setting of metastatic castration-resistant prostate cancer" [1349]. In this retrospective study, low PSMA uptake (≥1 lesion with no-to-low PSMA uptake) was seen on >50% of scans, and heterogeneous uptake (defined as both low and high PSMA uptake lesions on the same scan) was seen on >40% of scans. The authors concluded that this high degree of heterogeneity within patients and in low PSMA-expressing tumors may complicate treatment, particularly with PSMA-targeted radioligand therapy.

Maliha et al. from McGill University Health Center, the University of Montreal, and the Jewish General Hospital (all in Montreal, Canada) reported on "Physiological DCFPyL PSMA-targeted tracer uptake in the epididymis head newly appreciated on digital PET/CT" [1321]. This was an interesting incidental finding, and the authors noted that it is both common and more frequent in patients with higher serum testosterone levels. They emphasized that this physiologic finding should not be misinterpreted as pathologic.

Lindenberg et al. from the National Cancer Institute (NCI), the University of California San Francisco, Johns Hopkins University School of Medicine (Baltimore, MD), Yale University (New Haven, CT), and Novartis Pharmaceuticals (East Hanover, NJ; Turin, Italy; and Geneva, Switzerland) reported on "Safety and tolerability of $^{68}$Ga-PSMA-R2 as an imaging agent in patients with biochemical recurrence or metastatic prostate cancer" [1319]. In this safety and tolerability study, the PSMA agent was well tolerated with no significant adverse events. The authors concluded that the lesion detectability and low radiation dose absorbed by salivary and lacrimal glands compared with other PSMA PET agents are promising for future therapeutic applications.

Miksch et al. from University Hospital Ulm, the Technical University Munich (Garching), and the German Armed Forces Hospital Ulm (all in Germany) reported that "Novel $^{18}$F-siPSMA-14 shows favorable kinetics and high interobserver agreement in staging of prostate cancer patients" [1328]. The study analyzed biodistribution, detection rates, and interobserver agreement in 134 patients with either primary prostate cancer or recurrent disease. On a 5-point grading system, good agreement was noted (94% in primary and 86% in recurrent disease). As in previous abstracts, higher detection rates were found with higher PSA levels. No forced diuresis was used in the study. Target-to-nontarget ratios were notably high in PET/CT-positive tumors (9.3 in prostate, 11.6 in lymphatic, 14.3 in bone, and 14.6 in visceral lesions), enabling excellent contrast imaging. This contrast is evident in Figure 5 in a patient assessed for primary disease after chemotherapy. On the left, excreted activity in

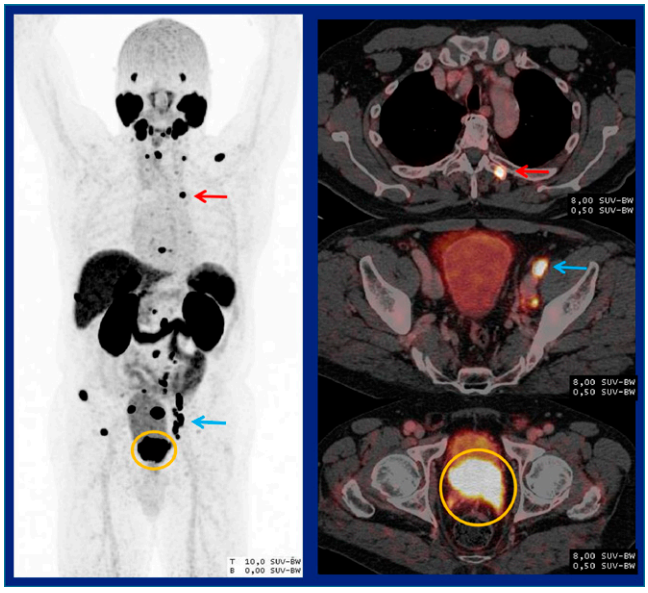


**FIGURE 5.** $^{18}$F-siPSMA-14 in staging prostate cancer patients. Images acquired in a 64-year-old man with progressive disease after chemotherapy (prostate-specific antigen = 100 ng/mL). Left: excreted activity on PET in the urinary bladder obscures the primary tumor. Right: contrast is high on $^{18}$F-siPSMA-14 PET/CT for bone (top), lymph node metastases (middle), and (although some excreted activity is seen in the bladder) much higher uptake is apparent in the primary tumor (bottom).

the urinary bladder obscures the primary tumor; on the right, contrast is high for bone and lymph node metastases and, although some excreted activity is seen in the bladder, much higher uptake is apparent in the tumor. This tracer is especially promising, then, for detecting locoregional recurrence.

### *Other Applications*

Naghavi-Behzad et al. from the University of Southern Demark (Odense), Odense University Hospital (Odense, Denmark), the Basel Academy for Quality and Research in Medicine (Switzerland), and the Technical University of Munich (Germany) reported on "Response monitoring in metastatic breast cancer: A comparison of survival times between FDG PET/CT and contrast-enhanced CT" [129]. This study is relevant to a challenge with which many of us deal on a day-to-day basis in our practices: arguing with insurance companies about whether a scan should be preapproved for reimbursement. Patients in the study underwent conventional imaging with contrast-enhanced CT (144 patients), FDG PET/CT (83 patients), or both (72 patients) as part of response monitoring to treatment. Their results indicated that overall, 5-year survival rates for patients with metastatic breast cancer were significantly higher with PET/CT alone (41.9%) or in combination with contrast-enhanced-CT (43.3%) than with contrast-enhanced CT alone (15.8%). Why would patients with PET imaging have better survival? The answer, of course, is that the improved survival is not related to the modality per se but to the fact that PET enables earlier detection of recurrence and more timely and appropriate management decisions. This study is clear evidence of the utility of PET/CT in response assessment in patients with breast cancer and provides the kind of quantitative data that may prove persuasive to third-party payers.

## Clinical Therapies

Great advances are being reported in clinical therapies in our field, highlighted this year by 2 recent clinical trials in patients with advanced prostate cancer. Results from the VISION trial were reviewed on June 6 at the American Society of Clinical Oncology (ASCO) meeting by Michael Morris, MD, from Memorial Sloan Kettering Cancer Center (New York, NY). The study has primary endpoints comparing radiographic progression-free survival and overall survival in patients with progressive PSMA-positive metastatic castrate-resistant prostate cancer who receive $^{177}$Lu-PSMA-617 in addition to best supportive/best standard of care versus patients treated with best supportive/best standard of care alone. The study enrolled patients who had positive PSMA signals on PET imaging and who had previously received taxane therapy and novel androgen axis therapy and were now deemed eligible only for best supportive care. It is important to point out that no PSMA-only arm was included in the study. Both the ASCO presentation and recently published results show that the treatment arm in the VISION trial had better overall survival and better radiographic progression-free survival with improved quality of life. We look forward to more analyses and results from this trial.

The next trial was the TheraP trial, which had some important differences from the VISION trial. Hofman et al. from the Peter MacCallum Cancer Centre/University of Melbourne, St. Vincent's Hospital and Garvan Institute of Medical Research (Sydney), Royal Brisbane and Women's Hospital (Brisbane), Royal Adelaide Hospital, Sir Charles Gairdner Hospital Western Australia (Nedlands), Calvary Mater Newcastle, Austin Health Melbourne, Monash Health (Melbourne), and Fiona Stanley Hospital (Murdoch; all in Australia) reported at the SNMMI meeting on "$^{177}$Lu-PSMA-617 versus cabazitaxel in metastatic castration-resistant prostate cancer: A randomized, open-label, phase 2 trial (TheraP)" [1703] (*9*). Patients with progressive disease after docetaxel therapy at 11 sites in Australia were first imaged with both $^{68}$Ga-PSMA and $^{18}$F-FDG PET/CT. Only those with positive PSMA uptake that was concordant with FDG uptake were included in the trial. A resulting total of 200 men were then randomized to $^{177}$Lu-PSMA-617 or cabazitaxel. Figure 6 includes examples from the study illustrating the concordant and discordant imaging findings used in patient selection. The patient on the top left, for example, showed low PSMA uptake and high FDG uptake, and so was ineligible for the trial. Next is a patient who had positive uptake of both tracers but with additional metastases seen only on FDG, a discordance that made the patient ineligible. This is in contrast to the eligible patients (bottom row) with concordant uptake on both scans and with PSMA-dominant findings. Imaging, then, was used to maximize the inclusion of patients most likely to benefit from $^{177}$Lu-PSMA-617 treatment. $^{177}$Lu-PSMA-617 led to significantly greater PSA reductions (66% experienced ≥50% reduction in PSA from baseline, compared with only 37% with cabazitaxel), higher objective response rates (49% vs. 24%; RECIST 1.1), longer progression-free survival at 1 year (19% vs. 3%), and significant improvements in several patient-reported outcome domains. Of note, the investigators also reported on comparative side effects. Patients in the $^{177}$Lu-PSMA-617 arm experienced fewer grade 3 or 4 adverse events (53% vs 33%) and overall reported fewer side effects. We look forward to seeing immediate benefits with this life-saving and quality-of-life-improving treatment for our patients with prostate cancer. [*Author's note:* On the same day this lecture was given, the U.S. Food and Drug Administration announced that it had granted Breakthrough Therapy designation for $^{177}$Lu-PSMA-617 in metastatic castration-resistant prostate cancer.]

In the context of radionuclide therapies, dosimetry is very important for both normal organs/tissues and target lesions. The process, however, can be quite time-consuming, requiring multiple scans on several subsequent days. Investigators across the globe are looking for solutions, particularly at whether advanced computational modeling can be used to derive dosimetry data with reasonable accuracy from a single time-point scan. Chicheportiche

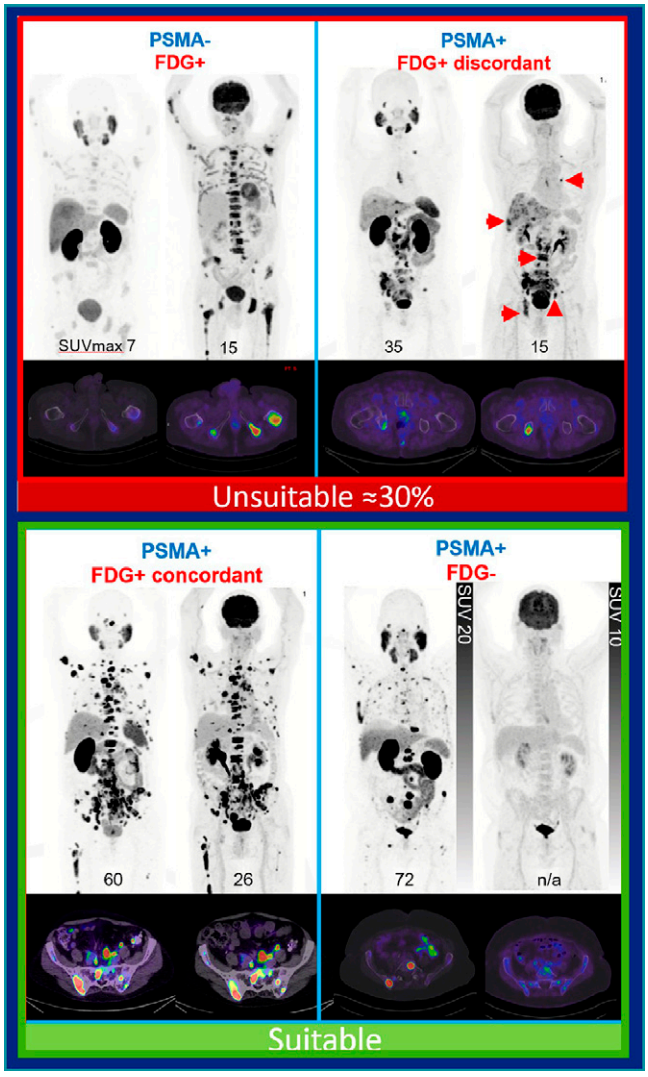


**FIGURE 6.** $^{177}$Lu-PSMA-617 vs cabazitaxel in metastatic castration-resistant prostate cancer: TheraP trial. Patients with progressive disease after docetaxel therapy were first imaged with both $^{68}$Ga-PSMA and $^{18}$F-FDG PET/CT, and only those with positive PSMA uptake that was concordant with FDG uptake were included in the trial. Images show PET (top) and PET/CT (bottom row) illustrating concordant and discordant findings used in patient selection. Top box: A patient with low PSMA uptake and high FDG uptake (left, ineligible for the trial); patient with positive uptake of both tracers but additional metastases seen only on FDG (right, discordant, ineligible). Bottom row: patient with concordant uptake on both scans (left, eligible); and patient with PSMA-dominant findings (right, eligible). Imaging was used to maximize inclusion of patients most likely to benefit from $^{177}$Lu-PSMA-617 treatment.

et al. from Hadassah–Hebrew University Medical Center (Jerusalem, Israel), Hebrew University of Jerusalem (Israel), and University College London/UCL Hospitals NHS Trust (London, UK) asked "Can absorbed radiation doses by organs and tumors after peptide-receptor radionuclide therapy (PRRT) be estimated from a single SPECT/CT study?" [18]. The aim was to assess the feasibility of using a single quantitative SPECT/CT study after each PRRT cycle combined with a trained multiple linear regression model for absorbed dose calculation. The researchers found that in

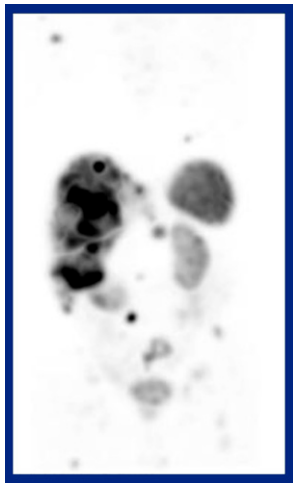

**FIGURE 7.** Single-timepoint imaging for dosimetry in peptide-receptor radionuclide therapy (PRRT). Researchers used a trained model for dose calculation with a single quantitative SPECT/CT study after each PRRT cycle for absorbed dose calculation (example image shown). The method was in good agreement with the standard multi-timepoint imaging protocol, with no associated changes in management decisions.

a test set with data from 40 patients, their dosimetry calculation method was in good agreement with the standard multi-timepoint imaging protocol, with no associated changes in management decisions (Fig. 7). The conclusion was that if this can be confirmed in a larger series it may very well be possible to perform a single scan to derive accurate dosimetry for PRRT and potentially other applications. This would result not only in simplification of the dosimetry process but also improved patient comfort and reduced scanner and staff time.

Interest continues in using nonimaging tools to improve our ability to predict and measure response to therapies. Blood-based molecular gene signatures are being incorporated into noninvasive tools to provide clinical guidance and facilitate management during PRRT, which may prove especially useful, because radiographic pseudoprogression is a known confounding factor during PRRT. Bodei et al. from Memorial Sloan Kettering Cancer Center (New York, NY), Wren Laboratories (Branford, CT), and Yale University School of Medicine (New Haven, CT) reported on "Blood-based genomic assessment of the clinical efficacy and toxicity of PRRT" [78]. These researchers used 3 independent blood-based gene expression assays: a 51-marker gene NETest (liquid biopsy) to monitor therapeutic efficacy, PRRT Predictor Quotient (a molecular marker used to predict PRRT responsiveness), and a 16-gene radiation toxicity assay to assess PRRT-related toxicity. In a cohort of $^{177}$Lu-PRRT–treated patients with gastroenteropancreatic neuroendocrine and lung tumors, these assays were explored for their suitability in predicting treatment response, monitoring response, or use as safety biomarkers to monitor renal function and predict toxicity. Each of the assays showed quite positive results. This is a work in progress, and series with larger numbers are forthcoming. If validated, this will be a helpful tool in predicting and monitoring patient response to DOTATATE therapy in neuroendocrine tumors.

Morgan et al. from the University of Colorado Medical Center (Aurora) reported on "Utilization and cost of

$^{223}$Ra-dichloride (Xofigo) for treatment of metastatic castration-resistant prostate cancer in the U.S. Medicare population" [1309]. This is an interesting study because the authors looked not only at utilization patterns from 2015 to 2017 (a period during which they noted a significant increase) but at which physicians/disciplines were actually administering the therapy. More than 57% of treatments were administered by radiation oncologists. This seems to be a clear call to action for the nuclear medicine community. Two years ago, Czernin et al. published an article in *The Journal of Nuclear Medicine* highlighting potential weaknesses and challenges for nuclear medicine, including insufficient training, loss of ownership, and lack of desire to perform theranostic applications or to perform therapy (*10*). There is a reason that the word "medicine" is in the name of our discipline—we encompass both diagnosis and therapy. We can continue to administer therapy and expand the range of these activities only if we as a community have the collective desire to do so, as well as the skills, infrastructure, and training programs. This is an appeal to all nuclear medicine professionals to work together to remain as owners of our therapy and theranostic applications.

*Part 2 of the 2021 Oncology and Therapy Highlights, in the November issue of Newsline, will focus on new targets for radionuclide therapy and other novel therapy approaches, as well as new techniques and methods for data analysis.*

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# SNMMI and ACGME Equity Matters Initiative

SNMMI announced on August 4 its partnership with the Accreditation Council for Graduate Medical Education (ACGME) in ACGME Equity Matters, a new initiative that introduces a framework for continuous learning and process improvement in diversity, equity, inclusion, and antiracism practices. The initiative aims to drive change within graduate medical education by increasing physician workforce diversity and building safe and inclusive learning environments, while promoting health equity by addressing racial disparities in health care and overall population health.

The ACGME Equity Matters framework includes 2 key components: (1) educational resources that will be available to all involved in GME; and (2) collaborative Learning Communities drawn from national stakeholder groups made up of GME Sponsoring Institutions and programs, including faculty members and individual residents/fellows, as well as specialty societies and other health care partners. The Council of Medical Specialty Societies (CMSS), of which SNMMI is a member, and the Organization of Program Director Associations (OPDA) launched their participation in the program with the convening of 2 Learning Communities that will initiate an 18-mo engagement cycle. This partnership will support diversity, equity, inclusion, and antiracist practices and policies across the full continuum from physician training to physicians in practice. Core teams from CMSS and OPDA members will include an elected leader to champion the initiative and senior executive leaders who will be accountable for implementing policy and practice changes.

The ACGME program will offer a phased curriculum to enable participants to move through progressively more complex concepts within 4 domains: acknowledgment, acceptance and accountability, action, and assessment and adaptation. Also included will be tools and skills training to drive implementation of innovative interventions, practices, policies, and data strategies. Forty-two organizations, including 31 CMSS Member Specialty Societies and 11 PDAs, will be participating in the inaugural 18-mo cohort of the learning communities. More information is available at: https://acgme.org/What-We-Do/Diversity-Equity-and-Inclusion/ACGME-Equity-Matters/.

*SNMMI*
*ACGME*

# Amnon (Amy) Piepsz, MD (1938–2021)

Amnon Piepsz was born in 1938 in Antwerp (Belgium) and died in Brussels (Belgium) on July 26, 2021, after a 2-year illness. He completed his studies in pediatrics in 1967 at the Vrije Universiteit Brussel (VUB) and became interested in nuclear medicine methodologies very early in his career, attracted by its physiologic and noninvasive approach. He completed his studies in nuclear medicine in 1969 at the VUB and advanced there rapidly to become a full professor of both pediatrics and nuclear medicine. His PhD thesis in 1988 was on a "Methodology of separate clearance measurement by means of $^{99m}$Tc-DTPA and the gamma camera."

Dr. Piepsz radiated enthusiasm for nuclear medicine throughout his career and was a major contributor to the "Consensus report on quality control of quantitative measurements of renal function obtained from the renogram" (*Semin Nucl Med.* 1999; 29:146–159), published by the International Scientific Committee of Radionuclides in Nephrourology (ISCORN). His main areas of interests are reflected in more than 250 peer-reviewed publications and were directed toward development of clearance methodologies in children and adults and both experimental and clinical studies related to pediatric nephrourologic problems.

He worked as a pediatrician in a general outpatient clinic with special interests in urinary tract infections, the mother–child relationship, and psychosomatic diseases. Most of his career was spent at the Centre Hospitalier Universitaire Saint-Pierre (Brussels, Belgium) and in the Academic Hospital of the VUB. After his official retirement, he continued to work as a volunteer at Ghent University Hospital, where he pursued his research and the education of trainees.

Dr. Piepsz became a genuine world citizen, giving lectures and courses in such diverse locales as Bombay, Cape Town, Djakarta, and Paris. He also lectured under the sponsorship of the International Atomic Energy Agency, the European School of Nuclear Medicine (European Association of Nuclear Medicine [EANM]), and the Université Paris-Sud. In addition, he was active in supporting the development of nuclear medicine in many less developed countries and in South America, especially Chile. He was fluent in multiple languages, including French, Flemish, German, English, Italian, and Spanish and loved to visit cities to become familiar with their inhabitants and cultures.

He was an active member of the Societies of Nuclear Medicine and of Pediatrics of Belgium and of the EANM. He was the beloved chair of the Paediatric Task Group of the EANM, on which he served for more than 20 years. He served as an editor of the *European Journal of Nuclear Medicine* and a scientific reviewer for *The Journal of Nuclear Medicine* and many other journals. He also coedited *Functional Imaging in Nephro-Urology* (London, UK: Taylor and Francis; 2006) under the auspices of ISCORN.

His life outside of medicine was rich. As a 15-year-old, he earned First Prize in piano at the Conservatoire Royal de Musique of Brussels. An extraordinary pianist, he played a wide range of music with expertise and feeling. He gave private concerts in duet with a violinist and also sang bass in the European Union Choir (of which he was president from 1999–2004). He was a lover of art and liked to swim, play tennis, and hike in the mountains with colleagues.

His nickname, Amy, perfectly characterized his generous personality ("ami" being French for "friend"). He had qualities rarely seen in a single person and was an inspirational figure for all in nuclear medicine. He was especially attentive to trainees and eager to share his scientific knowledge and clinical hands-on techniques. He was far more than an imaging specialist; he was an attentive clinician and sympathetic physician who was devoted to his pediatric patients, their parents, members of his department, and his collaborators. He always shared his enthusiasm and joy with others. We will miss him and remember him fondly.

*Alain Prigent, MD, PhD*
*Paris, France*
*M. Donald Blaufox, MD, PhD*
*New York, NY*
*Andrew Taylor, MD*
*Atlanta, GA*
*Naomi Alazraki, MD*
*Atlanta, GA*

# State of the Society: SNMMI Thrives Despite COVID-19 Challenges

*Virginia Pappas, CAE, SNMMI CEO*

Over the past year, SNMMI has navigated the most difficult operating environment we have experienced in our history. Throughout the year, SNMMI's board of directors and management team collaborated closely to enable the organization to deliver services to our members and meet the health and safety needs of our employees, then move above and beyond to conceive and implement new, exciting programs and ideas.

From the start of the pandemic, SNMMI took precautions to ensure the safety of members and staff, changing meetings to virtual formats and creating a new, effective work environment for staff and society operations. With SNMMI's already extensive experience in the virtual environment, these functions not only proved engaging and effective but also expanded our presence in the nuclear medicine space worldwide.

At the same time, the society worked closely with federal organizations and other groups on COVID-related issues, including vaccination priority for members and the availability of essential isotopes and amino acid solution. SNMMI also created an online COVID-19 Resource Center to ensure that members had the news, information, and advice they needed to support them in their practice.

Despite the challenges of the pandemic, SNMMI has advanced not only our existing projects but also a wide range of new initiatives. To promote advances in radiopharmaceutical therapy, a Radiopharmaceutical Therapy Centers of Excellence program and a Radiopharmaceutical Therapy Registry have been created. A therapy toolkit for sites beginning implementation has been developed, as well as practice resources, education, and information regarding dosimetry. New research fellowships, awards, and a technologist therapy badging program are now available or in progress. Much of this information can be found on the new RPT website portal at www.snmmi.org/therapy.

SNMMI has launched a new initiative to increase awareness of nuclear medicine among referring physicians and the general public, utilizing broad-based consumer media outreach. The society has also promoted cutting-edge research via *The Journal of Nuclear Medicine*, which dramatically increased its impact and influence among 133 medical journals in the medical imaging category.

In the health policy and regulatory affairs area, the FIND Act of 2021 was introduced in both the House of Representatives and the Senate. If passed, this legislation would significantly expand patient access to a wide range of diagnostic radiopharmaceuticals that can better detect conditions such as heart disease, Alzheimer and Parkinson disease, breast and prostate cancer, and neuroendocrine tumors. This legislation would also help providers better manage costs while delivering more targeted and cost-efficient care.

Years of work from SNMMI and its partners also paid off this summer as the Centers for Medicare and Medicaid Services (CMS) and Humana allowed coverage for noncologic PET imaging. In addition, with the retirement of the National Coverage Determination for $^{18}$F-FDG PET infection and inflammation, coding barriers have been removed and coverage determinations are now made by local Medicare Administrative Contractors. CMS is also considering new coverage for beta-amyloid imaging, which is supported by SNMMI.

Understanding that artificial intelligence will greatly impact the future of medicine, SNMMI has created several related initiatives. An Artificial Intelligence Taskforce, formed earlier this year, launched a challenge in conjunction with the Michael J. Fox Foundation to collect clinical data from DaTScan images. The task force has also been drafting manuscripts for submission to *JNM* and planning for an Artificial Intelligence Summit to be held in early 2022.

During the pandemic, fantastic progress has been made in the development of new agents and therapies, setting up the profession for increasing growth. Looking forward, we hope to hold events in-person to support this growth, including the Therapeutics Conference, November 11–14, 2021, in New Orleans, LA, and the Mid-Winter Meeting, January 28–31, 2022, in Orlando, FL.

I am proud to share with you that the decisions we made have put SNMMI on track to end fiscal year 2021 with very healthy positions of operating cash and investments. We are extremely grateful for our leadership, members, volunteers, corporate partners, and employees who have come together during this challenging time to enable SNMMI to continue to promote the value of nuclear medicine, molecular imaging, and radionuclide therapy. The innovative programs and services developed were extraordinarily successful and have allowed the society to remain healthy and strong.

## HHS Inspector General to Review FDA Accelerated Approval Pathway

The Office of Inspector General (OIG) of the U.S. Health and Human Services announced on August 4 that it would launch a review process of the recent U.S. Food and Drug Administration (FDA) approval of Aduhelm (aducanumab) to treat patients with Alzheimer disease under the accelerated approval pathway. The pathway allows the FDA to approve drugs that treat serious conditions and that fill an unmet medical need based on a surrogate endpoint. According to an OIG press release, this approval "raised concerns due to alleged scientific disputes within the FDA, the advisory committee's vote against approval, allegations of an inappropriately close relationship between the FDA and the industry, and the FDA's use of the accelerated approval pathway." In the review, the OIG will assess how the FDA implements the accelerated approval pathway and manages interactions with outside parties, as well as other aspects of the process, such as deciding how scientific disputes are resolved. FDA's relevant policies and procedures, along with compliance, will be included in the review, based on a sample of drugs approved using the accelerated pathway. The OIG will not assess the scientific appropriateness of the FDA approval of any drugs under review. This work may result in multiple reports, expected to be issued in 2023.

*Office of Inspector General*
*U.S. Health and Human Services*

## FIND Bills in House and Senate

On July 16, Congresspersons Scott Peters (D-CA), Bobby Rush (D-IL), Neal Dunn (R-FL), and Greg Murphy (R-NC) introduced the Facilitating Innovative Nuclear Diagnostics (FIND) Act of 2021 (HR 4479), intended to significantly expand patient access to advanced nuclear diagnostic imaging technologies. The bill (previously HR 3772) targets creation of a legislative fix to the Center for Medicare and Medicaid Services (CMS) bundling of diagnostic radiopharmaceuticals in the hospital outpatient space after a 3-year pass-through period postapproval by the U.S. Food and Drug Administration.

SNMMI and its coalition partners, the Medical Imaging & Technology Alliance and the Council on Radionuclides and Radiopharmaceuticals, in addition to dozens of patient advocacy organizations, praised the proposed legislation. "Innovative radiopharmaceuticals are revolutionizing the diagnosis and treatment of a wide variety of diseases, but under current CMS payment policies, these remarkable agents often are not available to Medicare beneficiaries, resulting in inequities in health care. The FIND Act addresses this current important problem and will improve access to these life-saving imaging agents," said Richard Wahl, MD, president of SNMMI.

"America leads the world in medical research and innovation—but far too often, patients are unable to access the benefits of innovative medical technologies because of outdated Medicare reimbursement policy," added Representative Dunn at the act's introduction. "The FIND Act is a common-sense, bipartisan proposal to address these current reimbursement problems, giving patients access to the diagnostic tools they need, when they need them. Early detection saves lives and we must do what we can to expand access to these life-saving tools."

On August 4, Senators Marsha Blackburn (R-TN) and Tammy Baldwin (D-WI) introduced a companion bill in the U.S. Senate (S. 2609). "Innovative technology like diagnostic radiopharmaceuticals are important tools in detecting and treating diseases such as cancer and Alzheimer's," said Senator Blackburn. "The FIND Act would increase patient access to more cost-effective treatment options while promoting further research and development opportunities for medical manufacturers."

The FIND Act addresses structural issues in the packaging methodology used in the Medicare outpatient setting by directing the Department of Health and Human Services to pay separately for all diagnostic radiopharmaceuticals with a cost threshold per day of $500. If passed, this bill would give patients greater access to a wide range of diagnostic radiopharmaceuticals that can better detect conditions such as heart disease, Alzheimer and Parkinson disease, breast and prostate cancer, and neuroendocrine tumors. This legislation would also help providers better manage costs while delivering more targeted and cost-efficient care.

For more information on the FIND Act, including avenues for advocacy, please see: https://www.snmmi.org/IssuesAdvocacy/content.aspx?ItemNumber=34002&navItemNumber=34003.

*SNMMI*

## New NIA Alzheimer Trial Recruitment Tool

The National Institute on Aging (NIA) announced on July 30 at the annual meeting of the Alzheimer's Association International Conference a new online research tool to help increase participation by traditionally underrepresented populations in clinical trials focusing on Alzheimer disease (AD) and related dementias. Called Outreach Pro, the tool will enable researchers to create and customize participant recruitment communications, such as websites, handouts, videos, and social media posts.

"We are facing a critical and growing need for people living with Alzheimer's and related dementia, as well as those at higher risk, and healthy people, to participate in clinical trials," said NIA Director Richard J. Hodes, MD. "That need is especially acute for frequently underrepresented groups such as Black and Hispanic Americans, which is why Outreach Pro includes an emphasis on helping clinical trial

researchers connect with these and other important communities."

Outreach Pro is one of a suite of NIA efforts to implement the National Strategy for Recruitment and Participation in Alzheimer's and Related Dementias Clinical Research (2018). To use Outreach Pro, researchers and clinicians first select desired templates with 1 of 3 communication goals: (1) to educate about AD, related dementias, and/or brain health; (2) to increase awareness and interest in AD and related dementias clinical trials; or (3) to provide information about a specific AD or related dementia clinical trial currently enrolling participants. Each template can be customized using a central library of messages, headlines, photos, and text that have been tested in individuals representing diverse and underserved populations. The materials will be available initially in English and Spanish, with plans for adding Asian American and Pacific Islander resources and languages later in 2021. Materials for American Indian and Alaska Native communities will be developed and added in 2022. NIA developed Outreach Pro and its content systematically by using literature reviews, environmental scans, listening sessions with stakeholders, focus groups, national surveys, and user testing. NIA plans to add content and scale up the tool's capabilities based on feedback and performance measurement.

In total, NIA is currently supporting 270 AD and related dementia clinical trials. Additional information on Outreach Pro is available at: https://outreachpro.nia.nih.gov/.

*National Institute on Aging*

## NIH Expands Biomedical Research in the Cloud

The National Institutes of Health (NIH) announced on July 10 that Microsoft Azure had joined the NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative as the newest cloud service provider to support biomedical research. Google Cloud and Amazon Web Services joined the initiative in 2018. The STRIDES Initiative aims to accelerate biomedical research in the cloud by reducing economic and process barriers as well as providing cost-effective access to cloud platforms, training, cloud experts, and best practices for optimizing research.

The initiative has already expanded access to critical infrastructure and cutting-edge cloud resources for NIH researchers, as well as NIH-funded investigators at more than 2,500 academic institutions across the United States. To date, NIH has helped more than 425 research programs and projects leverage cloud resources through the STRIDES initiative. Researchers have collectively used more than 83 million h of computational resources to access and analyze more than 115 petabytes of high-value biomedical data in the cloud. By leveraging the initiative, the National Library of Medicine's Sequence Read Archive (among the world's largest publicly available genome sequence repositories) migrated more than 43 petabytes of next-generation sequencing data to the cloud, easing access for millions of researchers. Researchers can now search the entire catalog of genomic data and take advantage of the computational tools for analysis.

A central tenet of the STRIDES Initiative is that data made available through these partnerships will incorporate standards endorsed by the biomedical research community to make data findable, accessible, interoperable, and reusable (FAIR). "NIH has an ambitious vision of a modernized, FAIR biomedical data landscape," said Susan K. Gregurick, PhD, associate director for Data Science and director of the Office of Data Science Strategy at NIH. "By partnering with Microsoft Azure, which has over 3 decades of experience in the cloud space, we can strengthen NIH's data ecosystem and accelerate data-driven research and discovery." Additional information is available at: https://datascience.nih.gov/strides/.

*National Institutes of Health*

## Medical Imaging Radiation Limits

On August 11 the American Association of Physicists in Medicine (AAPM), the American College of Radiology, and the Health Physics Society issued a joint statement in opposition to cumulative radiation dose limits for patient imaging, citing potential adverse effects on patient care. The statement comes in response to an opposing position by several organizations and recently published papers on the high-profile topic. According to the statement "the decision to perform a medical imaging exam should be based on clinical grounds, including the information available from prior imaging results, and not on the dose from prior imaging-related radiation exposures." In a related press release, AAPM stated its recommendation "against using dose values, including effective dose, from a patient's prior imaging exams for the purposes of medical decision-making. Using quantities such as cumulative effective dose may, unintentionally or by institutional or regulatory policy, negatively impact medical decisions and patient care." In addition, the position statement applied to "the use of metrics to longitudinally track a patient's dose from medical radiation exposures and infer potential stochastic risk from them." It does not apply to the use of organ-specific doses for purposes of evaluating the onset of deterministic effects (e.g., absorbed dose to the eye lens or skin) or performing epidemiologic research. The joint statement, a list of answers to frequently asked questions on the topic of medical radiation safety, and a list of references to research papers supporting the signatories' position is available at: https://www.aapm.org/org/policies/details.asp?id=1533.

*American Association of Physicists in Medicine*

## FDA and Collaborative Communities

The U.S. Food and Drug Administration (FDA) announced on August 4 participation in several new "collaborative communities" designed to address challenges in patient health care. Collaborative communities are continuing forums in which private and public sector representatives work together on medical device challenges to achieve common objectives and outcomes. "We're pleased to announce the progress we've made with participation in collaborative communities. These collaborations with diverse stakeholders are not only a strategic priority for the FDA's Center for Devices and Radiological Health, they also provide much needed forums for deep discussion and solution-driven initiatives to tackle important issues within the medical device ecosystem," said Jeff Shuren, MD, JD, director of the Center for Devices and Radiological Health. "The insights and outcomes developed by these groups will have long-standing impacts on public health."

The FDA currently participates in 12 collaborative communities, which are established, managed, and controlled by external stakeholders. These communities are collectively charting paths to accelerate and address regulatory science and other knowledge gaps to aid in medical device review and oversight. They may also impact the delivery of health care and change clinical care paradigms. The most recent collaborations focus on topics such as: medical device development and product quality; understanding of valvular heart disease; innovations in digital pathology; reducing rates of intended self-injury and suicidal acts by individuals with diabetes; and strategies to increase the awareness, understanding, and participation of racial and ethnic minorities in the medical technology industry.

Collaborative communities are convened by interested stakeholders and may exist indefinitely, produce deliverables as needed, and tackle challenges with broad impacts. The FDA does not establish, lead, or operate the communities, nor are they intended to advise the FDA. Instead, the FDA may participate in the community to contribute its knowledge and perspective to discussions of public health challenges and solutions. For more about the FDA and collaborative communities, see: https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together.

*U.S. Food and Drug Administration*

## Breast Cancer Risk in Health Professionals

In a study published on August 9 ahead of print in the *American Journal of Preventive Medicine*, Shen et al. from the Kaohsiung Municipal Ta-Tung Hospital, Kaohsiung Medical University Chung-Ho Memorial Hospital, and Kaohsiung Medical University (Kaohsiung City, Taiwan) and the Ministry of Labor (Taipei, Taiwan) reported on a 35-year longitudinal study of breast cancer risk among health professionals. The study included data from 4 country-wide population-based databases in Taiwan, including matched cohorts of 277,543 health professionals and 555,086 non–health professionals. The researchers found that health professionals had a significantly higher risk of breast cancer and that this elevated risk was associated with birth age, job tenure, rotating day/night work, and several specific health professional license types, including physician, pharmacist, registered nurse, midwife, medical technologist, and psychologist. The authors suggested that regular ultrasound for younger women health care professionals and mammography for those older than 45 y should be considered.

*American Journal of Preventive Medicine*