# PERSONALIZED MEDICINE AT FDA

## The Scope & Significance of Progress in 2022

PMC

# 2022 MILESTONES

1. Approval of 12 personalized medicines representing approximately 34 percent of all newly approved therapeutic molecular entities. Personalized medicines have now accounted for at least a quarter of new drug approvals for each of the last eight years. The approval trends suggest that personalized medicine has become a mainstay of health care across multiple disease states.

2. Approval of five new gene or cell-based therapies. Gene and cell-based therapies promise to dramatically improve care for certain patients by genetically re-engineering a patient's own cells to combat disease. The therapies approved in 2022 extend the benefits of these personalized treatment approaches to patients with rare genetic diseases including beta thalassemia, hemophilia B, and cerebral adrenoleukodystrophy, as well as those with cancers including refractory multiple myeloma and certain types of non-muscle invasive bladder cancer.

3. Clearance or approval of significant new or expanded indications for 12 diagnostic testing systems that can help target treatments to only those who will benefit, sparing expenses and side effects for those who will not. The newly cleared and approved indications include three new blood-based biomarker tests to guide personalized oncology treatment decisions. Those tests will expand the frontiers of minimally invasive liquid biopsies, which can be an alternative to tissue biopsies for some cancer patients. Several of the newly approved indications will also advance tumor-agnostic testing paradigms, which promise to extend the benefits of personalized medicine to more cancer patients by directing personalized medicines to all patients whose tumors express certain biomarkers, regardless of where in the body those tumors are located.

4. Approval of a new therapy to treat non-small cell lung cancers characterized by tumors with KRAS G12C genetic mutations. This marks the second targeted therapy for tumors with KRAS mutations, once considered resistant to drug therapy. The approval highlights the expanding scientific boundaries of personalized medicine.

5. Release of draft guidance documents titled ***Human Gene Therapy Products Incorporating Human Genome Editing*** and ***Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products.*** By providing recommendations for the development of certain types of human gene and cell-based therapy products, the documents promise to further enhance the efficiency with which product developers can develop submissions for this groundbreaking class of personalized treatments.

6. Approval of a new personalized therapy designed to treat patients with HLA-A *02:01 positive uveal melanoma, a rare eye cancer. The newly approved immunotherapy represents a new class of treatments called T-cell engagers, which bind to a protein found on the tumors of patients in order to elicit an immune response. The approval provides a precision oncology possibility for patients with few other treatment options.

# INTRODUCTION

While the health care system was still recovering from the immediate ramifications of the Covid-19 pandemic in 2022, the U.S. Food and Drug Administration advanced the frontiers of personalized medicine considerably with the efficient approval of new diagnostic tools and treatments that will expand the field with implications for patients with rare genetic diseases, cancers, and some common and infectious diseases.

Personalized medicine, sometimes called individualized or precision medicine, is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

With the approval of 12 new personalized medicines in 2022, personalized medicines have now accounted for at least a quarter of new drug approvals for each of the last eight years. This figure represents a sharp recent increase. Just a decade ago, personalized medicines accounted for less than 10 percent of the new therapies approved each year.

In 2022, FDA also expanded the indications for many existing personalized therapies; approved two new siRNA therapies; provided guidance on the development of gene and cell-based therapies while approving five such therapies for use; and approved several new diagnostic indications that will allow for targeted treatment decisions for various health conditions. These new technologies and policies will help innovators and physicians develop and provide safer and more efficacious treatments and prevention regimens based on the principles of patient-centered care.

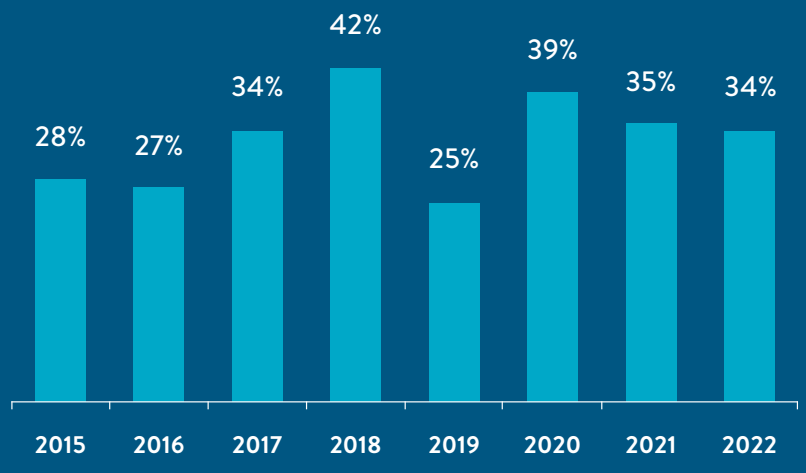
# A CONSISTENT TREND

## Personalized Medicines Account for More Than a Quarter of All New Therapeutics Approved Since 2015

FDA's Center for Drug Evaluation and Research (CDER) approved 37 new molecular entities (NMEs) in 2022. All but two of these NMEs are therapeutic products (the others were diagnostic agents). Of the 35 therapeutic NMEs, 12 of them — approximately 34 percent — are personalized medicines as classified by the Personalized Medicine Coalition (PMC). In 2021, personalized medicines accounted for 35 percent of newly approved NMEs. Personalized medicines now account for more than a quarter of the new therapeutics approved since 2015. They have comprised more than a third of new drug approvals for five of the last six years.

In addition, FDA's Center for Biologics Evaluation and Research approved five new gene or cell-based therapies in 2022. These approvals represent a significant advancement for this class of personalized treatments, which involve the transplantation of normal genes into a patient's own cells to modify specific cellular functions. FDA has now approved 13 gene or cell-based therapies.

## Personalized Medicines Accounted for More Than 25% of FDA Approvals for Each of the Last Eight Years




Methodology: When evaluating new molecular entities, PMC categorizes personalized medicines as those therapeutic products for which the label includes reference to specific biological markers, often identified by diagnostic tools, that help guide decisions and/or procedures for their use in individual patients.

# 2022 APPROVALS

## 12 of the 35 new therapeutic molecular entities FDA approved in 2022 — as well as five new gene or cell-based therapies — are personalized medicines.

1. Cibinqo (abrocitinib) — for the treatment of moderate to severe atopic dermatitis. The dosing of this product can be informed by the status of the CYP2C19 pharmacogenetic biomarker in patients.
2. Kimmtrak (tebentafusp-tebn) — for the treatment of unresectable metastatic uveal melanoma. The decision to use this product is informed by the status of the HLA-A *02:01 biomarker in patients.
3. Pyrukynd (mitapivat) — for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency. This product selectively targets the pyruvate deficiency (PK-mutated) biomarker in patients.
4. Opdualag (nivolumab and relatlimab-rmbw) — for the treatment of unresectable or metastatic melanoma. The use of this product can be informed by the status of the programmed death receptor-1 (PD-1) and lymphocyte activation gene-3 (LAG-3) biomarkers in the tumors of patients.
5. Pluvicto [lutetium (177Lu) vipivotide tetraxetan] — for the treatment of metastatic castration-resistant prostate cancer. The decision to use this product is informed by the status of the prostate-specific membrane antigen (PSMA) biomarker in the tumors of patients.
6. Amvuttra (vutrisiran) — for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis. This product is a small interfering RNA (siRNA) that selectively targets the transthyretin (TTR) mRNA biomarker in patients.

7. Xenpozyme (olipudase alfa) — for treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. This product selectively targets the sphingomyelin phosphodiesterase 1 biomarker in patients.
8. Lytgobi (futibatinib) — for the treatment of intrahepatic cholangiocarcinoma. The decision to use this product is informed by the status of the fibroblast growth factor receptor 2 (FGFR2) biomarker in the tumors of patients.
9. Elahere (mirvetuximab soravtansine-gynx) — for the treatment of recurrent ovarian cancer. The decision to use this product is informed by the status of the folate receptor alpha (FRα) biomarker in the tumors of patients.
10. Rezlidhia (olutasidenib) — for the treatment of relapsed or refractory acute myeloid leukemia. The decision to use this product is informed by the status of the isocitrate dehydrogenase-1 (IDH1) biomarker in the tumors of patients.
11. Krazati (adagrasib) — for the treatment of advanced or metastatic non-small cell lung cancer. The decision to use this product is informed by the status of the KRAS G12C biomarker in the tumors of patients.
12. Sunlenca (lenacapavir) — for the treatment of human immunodeficiency virus (HIV) infection in adults who cannot be successfully treated with other available treatments due to resistance, intolerance, or safety considerations. The use of this product can be informed by HIV-1 expression levels in patients.

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## Five Newly Approved Gene or Cell-Based Therapies

1. Carvykti (ciltacabtagene autoleucel) — for the treatment of adult patients with relapsed or refractory multiple myeloma after at least four prior lines of therapy. The treatment is a B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR)-positive T-cell immunotherapy.
2. Zynteglo (betibeglogene autotemcel) — for the treatment of adult and pediatric patients with beta thalassemia who require regular red blood cell (RBC) transfusions. The treatment is a cell-based gene therapy created using the patient's own bone marrow stem cells that are genetically modified to produce functional beta-globin product.
3. Skysona (elivaldogene autotemcel) — to slow the progression of neurologic dysfunction in pediatric patients with early, active cerebral adrenoleukodystrophy. The treatment is a cell-based gene therapy created using the patient's own hematopoietic stem cells (HSCs) modified to produce functional adrenoleukodystrophy protein (ALDP).
4. Hemgenix (etranacogene dezaparvovec-drlb) — for the treatment of adults with hemophilia B (congenital factor IX deficiency) who currently use factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes. The treatment is an adeno-associated viral vector-based gene therapy containing a transgene encoding a functional variant (R338L) of human factor IX under control of a liver-specific promotor 1 (LP1).
5. Adstiladrin (nadofaragene firadenovec-vncg) — for the treatment of adult patients with high-risk bacillus Calmette-Guérin-unresponsive non-muscle invasive bladder cancer with carcinoma in situ, with or without papillary tumors. The treatment is a non-replicating adenoviral vector-based gene therapy containing a transgene encoding the human interferon alfa-2b (IFNα2b).

## Other Important Trends in Drug Approvals

### Expanding Indications

Even the large number of new therapies classified as personalized medicines in 2022 does not provide the whole picture of the growing list of personalized medicines available to doctors and their patients. In addition to the 12 newly approved personalized NMEs and the five newly approved gene and cell-based therapies, FDA approved many significant new personalized medicine indications for existing drugs and combinations of drugs in 2022. These approvals redefine the drugs' intended populations and often provide patients with more effective personalized treatment options.

The list of new personalized medicines in 2022 should therefore be complemented with reference to newly approved indications and combinations for Opdivo (nivolumab), Lynparza (olaparib), Keytruda (pembrolizumab), Fintepla (fenfluramine), Yescarta (axicabtagene ciloleucel), Piqray (alpelisib), Ultomiris (ravulizumab-cwvz), Cuvrior (trientine tetrahydrochloride), Enhertu (trastuzumab deruxtecan), Vidaza (azacitidine), Tibsovo (ivosidenib) in combination with Onureg (azacitidine), Yervoy (ipilimumab) in combination with Opdivo (nivolumab), Kymriah (tisagenlecleucel), Tafinlar (dabrafenib) in combination with Mekinist (trametinib), Breyanzi (lisocabtagene maraleucel), Xalkori (crizotinib), Nubeqa (darolutamide), Tabrecta (capmatinib), Pemazyre (pemigatinib), Imfinzi (durvalumab), Orkambi (lumacaftor/ivacaftor), Retevmo (selpercatinib), and Pemfexy (pemetrexed).

Significant among these expanded indications are the expanded labels for Retevmo (selpercatinib) and the combination of Tafinlar (dabrafenib) and Mekinist (trametinib). Retevmo, previously approved for non-small cell lung cancer and thyroid cancers, is now indicated for the treatment of all solid tumors that have a RET fusion mutation. Tafinlar, previously approved for metastatic melanoma and non-small cell lung cancer indications, and Mekinist, previously approved for melanoma indications, now have expanded indications when used in combination for the treatment of all solid tumors that have an underlying BRAF V600E mutation. This provides more safe and effective targeted treatment options for many patients with less common tumor types for which a personalized medicine approach previously may not have been a consideration. With these expanded indications, there are now seven treatments that can be prescribed to cancer patients regardless of the tumor tissue of origin.

Also significant among these expanded indications, FDA approved a new non-oncology indication for previously approved breast cancer treatment Piqray (alpelisib). The PI3K inhibitor is now also indicated to treat PIK3CA-related overgrowth spectrum (PROS), a rare condition that causes blood vessel abnormalities and overgrowth of tissue primarily in pediatric patients. To treat PROS, alpelisib is branded as Vijoice. It becomes the first treatment specifically approved for the condition and demonstrates a rare expansion of a cancer drug to treat a non-oncologic rare condition.

# IMPACT

## Personalized Treatments Approved in 2022 Address a Spectrum of Health Conditions Including Rare Genetic Diseases, Cancer, and Some Common and Infectious Diseases

### Reversing the Root Causes of Rare Genetic Diseases

Three of the 12 newly approved NMEs and three of the five newly approved gene and cell-based therapies are designed to reverse the root causes of certain rare genetic diseases. Many patients with transthyretin-mediated amyloidosis, pyruvate kinase (PK) deficiency, acid sphingomyelinase deficiency, beta thalassemia, cerebral adrenoleukodystrophy, and congenital factor IX deficiency hemophilia B now have treatments available that target the underlying molecular mechanisms of their diseases.

Amvuttra (vutrisiran) provides a novel therapy for the treatment of hereditary transthyretin (hATTR) amyloidosis with polyneuropathy, a rare, progressive, and often fatal disease characterized by the extracellular buildup of an aberrant transthyretin (TTR) protein that accumulates in multiple organs throughout the body. The TTR buildup progressively contributes to physical debilitation and eventual morbidity.

Amvuttra is the latest siRNA therapy, a class of personalized medicines also known as gene-silencers. By disrupting the production of the TTR protein, it reduces the levels of TTR in the body, preventing transthyretin build-up and organ damage. The therapy need only be administered by injection once every three months, giving hATTR amyloidosis patients an effective treatment option that is easier to manage than existing therapeutic approaches. As such, the therapy promises to improve quality of life and significantly increase survival. The approval of the siRNA therapy also underlines the continued advancement of this treatment class and demonstrates how personalized medicine that targets underlying molecular causes can help physicians and patients get ahead of devastating rare diseases.

## Combatting Cancer

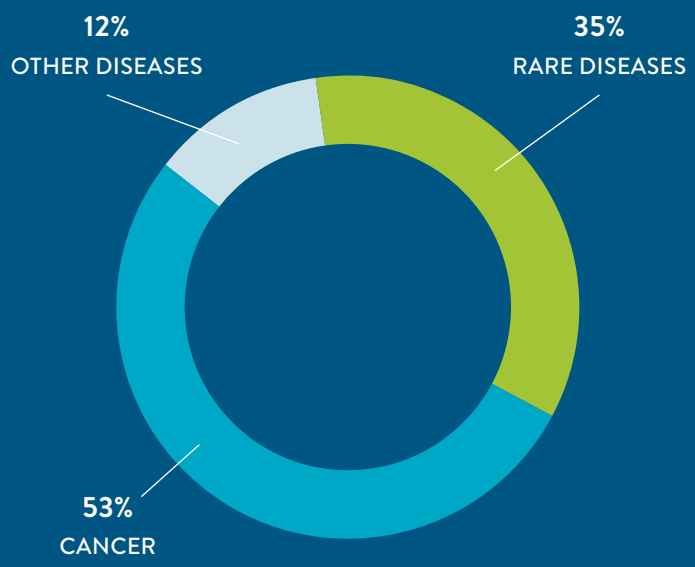
Seven of the 12 newly approved molecular entities and two of the five newly approved gene and cell-based therapies provide new treatment options for cancer patients, including two rare forms of cancer for which few treatment options were available. These treatments can significantly improve the outlook for many patients, reducing disease progression and extending survival.

The approval of Elahere (mirvetuximab soravtansine-gynx) for patients with folate receptor alpha (FRα) positive epithelial ovarian, fallopian tube, or primary peritoneal cancer marks the first approved targeted treatment for tumors with a FRα mutation, which occurs in 70 to 80 percent of recurrent ovarian cancers. FDA also approved the Ventana FOLR1 RxDx Assay as a companion diagnostic to select patients with the biomarker that are eligible to receive Elahere treatment. The drug is part of a class known as antibody drug conjugates and includes a FRα directed antibody attached to a microtubule inhibitor, which selectively targets tumor cells and induces cell death. The approval addresses a great unmet need for patients with recurrent ovarian cancer who previously had to endure multiple rounds of less effective chemotherapy and radiation therapy. The approval provides patients with a targeted treatment option that can improve their clinical outcomes through increased survival rates and fewer side effects.

Kimmtrak (tebentafusp-tebn) provides the first approved therapy for the treatment of metastatic uveal melanoma. Though rare in comparison to the prevalence of other cancer types, metastatic uveal melanoma is the most prevalent form of cancer that begins in the eye. Kimmtrak is one of a new class of drugs known as T-cell engagers. These therapies are designed to bind to a specific protein found on tumors. The binding calls forth a targeted immune response that can destroy cancerous cells. The drug combines a gp100 peptide that binds to tumor cells with a specific immune cell engager peptide and is indicated for the treatment of patients with a specific immune system signature known as HLA-A *02:01. Prior to the approval of Kimmtrak, uveal melanoma patients typically survived for 9 to 16 months after diagnosis. The approval of Kimmtrak has led to significantly improved survival rates, thereby demonstrating the utility of this new class of personalized immunotherapies.

## Newly Approved Personalized Medicines Are Indicated for Treatment of Cancer, Rare Diseases, and Common/ Infectious Diseases

Includes 12 New Molecular Entities and Five Newly Approved Gene and Cell-Based Therapies




**Cancer**

1. Adstiladrin*
2. Carvykti
3. Elahere
4. Kimmtrak*
5. Krazati
6. Lytgobi
7. Opdualag
8. Pluvicto
9. Rezlidhia

**Rare Diseases**

10. Amvuttra
11. Hemgenix
12. Pyrukynd
13. Skysona
14. Xenpozyme
15. Zynteglo

**Other Diseases**

16. Cibinqo
17. Sunlenca

*indicates rare cancer

# NEW DIAGNOSTICS

## Newly Approved/Cleared Diagnostic Indications Will Help Target Personalized Medicines to Those Most Likely to Benefit

An important consideration for personalized medicine is the use of diagnostics to discern biomarker statuses to guide drug use. In 2022, FDA's Center for Devices and Radiological Health and Center for Biologics Evaluation and Research approved or cleared several significant new or expanded indications within 12 in vitro diagnostic testing applications that underpin personalized medicine strategies. New approvals and expanded indications associated with the 12 tests listed below will help inform targeted treatment decisions to improve drug safety and efficacy.

### Significant New Approvals/Indication Expansions

1. FoundationOne® CDx — Five significant indication expansions, as follows:
   - indications expanded to include detection of BRAF V600 mutations to help guide decisions regarding the use of Tecentriq (atezolizumab) in combination with Cotellic (cobimetinib) and Zelboraf (vemurafenib) for the treatment of melanoma.
   - indications expanded to include detection of microsatellite instability-high (MSI-H) genomic signatures to help guide decisions regarding the use of Keytruda (pembrolizumab) for the treatment of solid tumors.
   - indications expanded to include detection of mutations in EGFR exon 19 deletions or exon 21 (L858R) substitution to help guide decisions regarding the use of Tarceva (erlotinib), Tagrisso (osimertinib), Iressa (gefitinib), Gilotrif (afatinib), or Vizimpro (dacomitinib) for the treatment of non-small cell lung cancer.

- indications expanded to include detection of ROS1 fusion mutations to help guide decisions regarding the use of Rozlytrek (entrectinib) for the treatment of non-small cell lung cancer.
- indications expanded to include detection of NTRK1, NTRK2, and NTRK3 fusions to help guide decisions regarding the use of Rozlytrek (entrectinib) for the treatment of solid tumors.

2. Ventana MMR RxDx Panel — Two significant indication expansions, as follows:
   - indications expanded to include measure of mismatch repair deficiency (dMMR) to guide decisions regarding the use of Keytruda (pembrolizumab) for the treatment of solid tumors.
   - indications expanded to include measure of mismatch repair proficiency (pMMR) to guide decisions regarding the use of Keytruda (pembrolizumab) in combination with Lenvima (lenvatinib) for endometrial carcinoma.
3. Abbott RealTime IDH1 — Approved for detection of IDH1 R132 mutations to guide decisions regarding the use of Rezlidhia (olutasidenib) for the treatment of acute myeloid leukemia.
4. Ventana FOLR1 (FOLR-2.1) RxDx Assay — Approved to measure FOLR1 protein expression to guide decisions regarding the use of Elahere (mirvetuximab soravtansine-gynx) for the treatment of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.
5. Therascreen KRAS RGQ PCR Kit — Indications expanded to include detection of KRAS G12C mutations to help guide decisions regarding the use of Krazati (adagrasib) for the treatment of non-small cell lung cancer and detection of KRAS wild-type (absence of mutations in codons 12 and 13) to help guide decisions regarding the use of Erbitux (cetuximab) for the treatment of colorectal cancer.
6. SeCore CDx HLA Sequencing System — Approved to detect the HLA-A*02:01 variant to guide decisions regarding the use of Kimmtrak (tebentafusp-tebn) for the treatment of uveal melanoma.

7. POMC/PCSK1/LEPR CDx Panel — Approved to detect POMC, PCSK1, and LEPR variants to help guide decisions regarding the use of Imcivree (setmelanotide acetate) for the treatment of obesity.

8. Oncomine Dx Target Test — Three significant indication expansions, as follows:
   - indications expanded to include detection of RET fusions to guide decisions regarding the use of Retevmo (selpercatinib) for the treatment of non-small cell lung cancer or thyroid cancer.
   - indications expanded to include detection of RET mutations (SNVs, MNVs, and deletions) to guide decisions regarding the use of Retevmo (selpercatinib) for the treatment of medullary thyroid cancer.
   - indications expanded to include detection of ERBB2 (HER2) activating mutations to guide decisions regarding the use of Enhertu (fam-trastuzumab deruxtecan-nxki) for the treatment of non-small cell lung cancer.

9. Guardant360 CDx — Indications expanded to include detection of ERBB2 (HER2) activating mutations from plasma samples to guide decisions regarding the use of Enhertu (fam-trastuzumab deruxtecan-nxki) for the treatment of non-small cell lung cancer.

10. Agilent Resolution ctDx FIRST assay — Approved to detect KRAS G12C mutations from plasma samples to guide decisions regarding the use of Krazati (adagrasib) for the treatment of non-small cell lung cancer.

11. FoundationOne® Liquid CDx — Indications expanded to include detection of EGFR exon 19 deletion or exon 21 (L858R) substitution mutations from plasma samples to guide decisions regarding the use of Iressa (gefitinib), Tagrisso (osimertinib), or Tarceva (erlotinib) for the treatment of non-small cell lung cancer.

12. PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody — Indications expanded to include measurement of HER2 protein expression to guide decisions regarding the use of Enhertu (fam-trastuzumab deruxtecan-nxki) for the treatment of breast cancer.

## The Significance of Liquid Biopsy

Blood-based tests continue to gain traction as an alternative to traditional solid tissue biopsy-based diagnostic tests for cancer. These tests allow cancer care providers to screen patients for the presence of cancer biomarkers from a simple blood sample in some cases where a tumor tissue biopsy cannot be obtained or where there is not enough high-quality tissue sample to be used for genetic testing. Liquid biopsy tests are also gaining traction for use in early detection of cancer and for monitoring relapse in cancer care.

As indicated above, in 2022, FDA approved the Agilent Resolution ctDx FIRST assay as a new diagnostic test that uses circulating tumor DNA in the blood to identify advanced non-small cell lung cancer patients with a KRAS G12C mutation who are eligible for RAS-targeted treatments. The FDA also expanded the indications of the FoundationOne Liquid CDx assay and the Guardant360 CDx assay to detect, from plasma samples, EGFR exon 19 deletion or exon 21 (L858R) substitution mutations and ERBB2 (HER2) activating mutations, respectively. The approval of these tests and indications further expands the liquid biopsy paradigm, providing valuable tools for the delivery of personalized medicine.

# POLICY PRECEDENT

## FDA Guidance on the Development of Gene and Cell-Based Therapies

Policymakers continue to try to help streamline processes for the development of gene and cell-based therapies. In 2022, FDA published two draft guidance documents on the subject, titled *Human Gene Therapy Products Incorporating Human Genome Editing* and *Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products*.

Recognizing the challenges of developing complex, multi-component gene and cell-based therapies, FDA outlined recommendations within these guidance documents that address preclinical and clinical testing, chemistry, manufacturing, and controls as well as information that should be included in investigational new drug applications (INDs). FDA recommends that gene and cell-based therapy product developers communicate with the Office of Tissues and Advanced Therapies in the Center for Biologics Evaluation and Research early in product development before submission of an IND, to discuss any product-specific considerations.

With the publication of these guidance documents, the agency has provided additional sources of information for product manufacturers as they develop this important class of therapies. The documents promise to help bring more personalized medicine technologies to market, faster.

# CONCLUSION

## Reshaping Health Care and Sustaining the Promise of Personalized Medicine

Despite ongoing challenges in the areas of scientific discovery, diagnostic regulatory policy, coverage, reimbursement, and clinical adoption, the developments at FDA in 2022 show that science is leading the health system away from one-size-fits-all, trial-and-error medicine, toward the utilization of molecular information to improve patient outcomes and make health care more efficient. Novel personalized medicine technologies promise to improve outcomes for patients and have a tremendous impact on the efficacy and efficiency of health care.

Continued progress cannot be taken for granted. To ensure that scientists and innovators continue to develop groundbreaking personalized medicine tests and treatments for the benefit of patients and health systems, policymakers, as they have in the past, must favor policies that encourage the advancement of the field.

# ABOUT US

The Personalized Medicine Coalition (PMC), representing innovators, scientists, patients, providers, and payers, promotes the understanding and adoption of personalized medicine concepts, services, and products to benefit patients and health systems.

PMC
PERSONALIZED
MEDICINE COALITION

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