in small populations but were not yet ready to make formal coverage decisions or support widespread adoption of specific technologies. Most payers were optimistic about the promise of digital health solutions, with the greatest expectations for chronic disease management. Skepticism about incremental value and costs led most respondents to desire stringent evaluation criteria and evidence standards, with standard benchmarks of value preferred. Most expected digital health solutions would need to demonstrate decreased costs and improved clinical outcomes. The most commonly desired attributes of digital health technologies are randomized clinical trial results, proven patient compliance, and EHR/EMR integration. **CONCLUSIONS:** Developing standardized evaluation criteria for digital health technologies will drive more consistent coverage outcomes and facilitate faster patient access to novel digital health technologies.

PMD64
COMPANION DEVICES: TRANSFORMATIVE MOBILE HEALTH TECHNOLOGY TOWARDS IMPROVED PATIENT CARE DELIVERY
Chawla AS[1], Paul A[1], Horowicz-Mehler N[2], Faulkner EC[3], Doyle JJ[4]
[1]Quintiles Consulting, Durham, NC, USA, [2]Quintiles Global Consulting, New York, NY, USA, [3]Institute for Pharmacogenomics and Individualized Therapy, Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC, USA, [4]Quintiles, Hawthorne, NY, USA
OBJECTIVES: Companion devices enable Mobile Health (mHealth) via remote monitoring of patients' biometrics. By 2020, the global mHealth market is estimated to reach $6.28 billion. While mHealth is expected to revolutionize delivery of patient care, especially for chronic diseases such as diabetes or asthma, it has not realized its full potential. To that end, the objectives of this study were to: 1) Characterize benefits that companion devices may deliver to key stakeholders, including patients, Health Care Professionals (HCPs), payers, and drug manufacturers; 2) Determine how HCPs currently utilize companion devices and key unmet needs; 3) Identify perceived roadblocks by payers in coverage & reimbursement of companion devices. **METHODS:** Health Technology Assessments (HTAs) and guidelines published between 2010 and 2014, and publications archived in MEDLINE and PubMed were analyzed to assess potential benefits, challenges, and historical valuation of companion devices. Additionally, approved companion devices were evaluated to assess their coverage and reimbursement and associated evidence requirements in the US and 5 major EU markets. **RESULTS:** Companion devices can potentially deliver benefits across the continuum of care that may be categorized into three areas: patient management (adherence and compliance), disease management (clinic visits and trend alerts), drug management (dosage and clinical events). Current barriers to adoption appear to be primarily cost of technology, potentially increased liability exposure, compliance with patient confidentiality, challenge in demonstrating positive budget impact, and importantly, lack of optimal reimbursement (separate vs bundled payment). **CONCLUSIONS:** While relatively nascent, companion devices are expected to play a role along the full continuum of patient care: from prevention, diagnosis, treatment, to monitoring. As such, this study indicated that the integration of companion devices with care plans is potentially hinged around three key issues: a) patient education and awareness, b) physician engagement via streamlined clinical workflow, and c) demonstration of long-term economic benefits to payers.

PMD65
UNIVERSAL SCREENING IDENTIFIES HIGHER THYROID DYSFUNCTION IN PREGNANCY. EVIDENCE BASED META-ANALYSIS
Sharma S[1], Bansal D[2], Gudala K[3]
[1]National Institute of Pharmaceutical Education and Research, mohali, India, [2]national institute of pharmaceutical education and reasearch, mohali, punjab, India, [3]National Institute of Pharmaceutical Education and Research, Mohali, India
OBJECTIVES: Pregnancy poses a high risk of thyroid dysfunction (TD) causing adverse outcomes in mother, fetus and neonate. This makes screening pregnant women for TD essential. Universal screening (US) aims to screen all women in contrast to targeted screening (TS) where only women at high-risk get tested for TD during pregnancy. Existing guidelines do not recommend US. Thus we performed meta-analysis to clarify this moot question whether US should be recommended for screening TD in pregnancy. **METHODS:** All original research articles comparing the two approaches to detect TD in pregnancy were searched from databases PubMed, EBSCO and Cochrane library. Effect estimate is reported as loss ratio (LR) signifying missed cases. Missed cases are women considered as low risk during TS. Subgroup analysis was done for hyperthyroid and overall thyroid disorder. Further sensitivity and specificity analysis was also done. Data is analyzed using CMA 2.0. **RESULTS:** Total of 9 studies including 10,888 women was included in present analysis. As significant heterogeneity was found between studies ($P < 0.001$, $I2 = 0.99$), random-effects model was used. 46% hypothyroid cases were missed if TS was performed instead of US (RR 0.46 (95% CI (0.35 to 0.61), $P \leq 0.001$). Sensitivity analyses showed (RR 0.40 (95% CI (0.27 to 0 0.55), $P \leq 0.001$) Specificity test has confirmed it (RR 0.31 (95% CI (0.20 to 0.47), $P \leq 0.001$). Similar trends were seen in hyperthyroid (RR 0.56 (95% CI (0.51 to 0.65), $P \leq 0.001$) and over-all TD (RR 0.49 (95% CI (0.43 to 0.60), $P \leq 0.001$). **CONCLUSIONS:** Almost half of the cases were missed on TS. The present pooled analysis recommends US to identify overall TD as well as hypothyroid cases in pregnancy. This serves as a strong evidence for inclusion of US into guidelines.

PMD66
CHARACTERIZATION OF EARLY STAGE BREAST CANCER PATIENT MANAGEMENT IN A PRACTICE SETTING WITH THE 21-GENE BREAST CANCER ASSAY
Pecora A[1], Waintraub S[1], Choi K[2], Chao C[3], Rothney M[4]
[1]Regional Cancer Care Associates, Hakensack, NJ, USA, [2]COTA, Inc., New York, NY, USA, [3]Genomic Health, Inc., Redwood City, CA, USA, [4]Genomic Health, Inc, Redwood City, CA, USA
OBJECTIVES: Patients with low risk 21-Gene Breast Cancer Assay results can safely avoid chemotherapy (CT), as has been shown in protocol-driven studies. This study's objective was to compare, using practice management data, CT and supportive drug therapy use in a practice setting in patients who did or didn't receive the assay. **METHODS:** Patients with initial visits for ER+, HER2- ESBC to the Regional Cancer Care Associates physician practice in 2009-2013 were identified using COTA, an oncology outcomes and cost tracking database. A case-control design was used to describe demographic, clinical, adjuvant CT, and supportive care therapy information for patients < 70 years. **RESULTS:** 158 Case patients who received the assay and 111 Controls who did not were identified. Cases were older, had larger tumors, and had more stage 1 tumors ($p < 0.05$). A significantly lower proportion in the Case group (21%) received CT compared to the Control group (56%; $p<0.001$). The proportions of N- Case patients who received CT were 2%, 33%, and 100% in the Low, Intermediate and High Recurrence Score groups, respectively. Fifty of the 269 patients (10 Cases, 40 Controls) were N+. In N+ Cases (n = 10), no Low risk group patients (n=6) received CT, while all Intermediate and High risk group patients did. The proportion of Case patients who received pegfilgrastim or aprepitant was significantly lower than in the Control group ($p<0.001$). The proportions of N+ Case patients receiving pegfilgrastim or aprepitant were also lower than in the N+ Control group. **CONCLUSIONS:** Physicians appear to be selective in using the 21-Gene assay in ESBC patients. Tested patients were less likely to receive CT and other supportive therapies. A majority of N+ patients tested had low Recurrence Score results and avoided CT, supporting potential utility of the assay in these patients.

PMD67
TRENDS IN ONCOLOGY BIOMARKER TESTING IN EUROPE (EU): OBSERVATIONS FROM BREAST CANCER (BC), METASTATIC NON-SMALL CELL LUNG CANCER (MNSCLC) AND METASTATIC COLORECTAL CANCER (MCRC)
Narayanan S[1], Butcher A[2]
[1]Ipsos Healthcare, columbia, MD, USA, [2]Ipsos Healthcare, New York, NY, USA
OBJECTIVES: Assess the trends in Human Epidermal Growth Factor Receptor 2 (HER2), Epidermal Growth Factor Receptor mutation (EGFRm) and KRAS biomarker testing in BC, mNSCLC and mCRC respectively in EU. **METHODS:** A multi-country retrospective medical chart-review of BC/mNSCLC/mCRC patients were conducted by cancer treating physicians in Germany/France/Spain/Italy (4EU) and the UK; Data collection period was BC:2004-2013, mNSCLC/mCRC:2009-2014. Physicians were recruited from a geographically representative sample in each country. Approximately 10-25 eligible patients in respective tumor types on usual care anti-cancer regimen were identified by each physician within each of the four-quarterly study observation-windows in respective years. Physicians abstracted data on patient demographics, disease status, treatment patterns and biomarker status .The analysis focused on HER2, EGFRm and KRAS testing trends. **RESULTS:** An average of 7500 BC (4EU~6000; UK~1500), 3600 mNSCLC (4EU~3000; UK~600) and 750 mCRC (4EU~600; UK~150) patient charts were abstracted per year. Percentage BC patients tested for HER2 increased in 4EU from 2004(70%) to 2009(89%) to 2013(97%), while the testing rates started relatively low in the UK initially (2004:23%; 2009:81%) and reached 4EU levels in 2013 (98%). EGFRm testing rates in mNSCLC increased in 4EU from December-2009(7%) to December-2011(53%) to December-2013(62%), and the UK testing rates increased during the corresponding period to be on-par despite starting slow (December-2009:2%; December-2011:33%; December-2013:62%). KRAS mutation testing rates in mCRC showed the largest difference between 4EU (December-2009:61%; December-2011:89%; December-2013:92%) and UK (December-2009:6%; December-2011:26%; December-2013:62%) throughout the evaluation period. **CONCLUSIONS:** HER2/EGFRm/KRAS biomarker testing rates initially lagged behind in the UK in comparison to Germany/France/Italy/Spain, and the difference existed throughout the study evaluation period for KRAS, while HER2/EGFRm testing rates converged in 2013. Factors influencing these observed patterns (incl. access to medicines with relevant indications) needs further scrutiny to facilitate optimal care delivery utilizing targeted oncology therapeutics to benefit patients.

PMD68
THE RISE OF THE VALUE ANALYSIS COMMITTEE AT US HOSPITALS, BETTER OR WORSE FOR MEDICAL DEVICE COMPANIES?
Hristova-Neeley D[1], Armstrong S[1], Garfield S[1], Ertel D[2]
[1]GfK Custom Research, Wayland, MA, USA, [2]Einstein Healthcare Network, Philadelphia, PA, USA
OBJECTIVES: In response to increased pressure to contain costs and optimize patient outcomes, hospitals have implemented standardized decision-making processes utilizing value analysis committees (VACs). In 2012, 64% of hospitals reported using some form of VAC. The objective of this analysis was to quantify the adoption of VAC, the product features considered impactful by VAC, timing of review and evidence requirements. **METHODS:** Qualitative interviews (n=40) and quantitative online survey (n=76) were conducted with C-suite executives, purchasers, and clinician leads in the second half of 2014. Research participants were drawn from across the US, from a diverse selection of hospitals, including large/small, rural/urban and profit/non-profit. Outcomes of the research included adoption of VAC, triggers for VAC review, timing of review process, evidence requirements and implications for medical device companies. **RESULTS:** 100% of hospitals surveyed report use of VAC for all new products being considered. Existing products may undergo a VAC when price or features change. Most products are brought to the VAC by the service line head, although one third of hospitals reported use of an automated system. Price of the product was identified as the most important consideration during VAC, though patient experience and other elements addressed by value-based purchasing were also mentioned. Clinical trial data was cited as most influential. However, most hospitals consider products in terms of their patient populations and specific context, making clinical trial data not optimally relevant to all hospitals. **CONCLUSIONS:** Because VACs are now a standard process at US hospitals, medical device companies must have a thorough understanding of the process and evidence requirements. Opportunities exist for increased communication between innovators and hospital decision-makers to align solutions with needs.Facility specific value propositions and data are frequently required to secure product approval.