they were completing it at their outpatient clinic. Such data collection must be tied to a transparent clinical purpose that patients see as an integral part of their health care. Other avenues for collecting outpatient drug toxicities outcomes should be further explored.

PCN231
DO PATIENT REPORTED OUTCOMES (PRO) IN ONCOLOGY MATTER IN HEALTH TECHNOLOGY ASSESSMENTS (HTA)?
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1Quintiles, Barcelona, Spain, 2Quintiles, Reading, UK
OBJECTIVES: To assess the importance of PROs in HTA in oncology. Our aim was to compare the HTA agencies from European countries in which PROs are included in the clinical trial review compared to those in which PROs are not.
RESULTS:Our study showed that PROs are included in HTA in 14 European countries: Austria, Belgium, Denmark, Germany, France, Italy, the Netherlands, Spain, Switzerland, Sweden, Portugal, Spain, Spain and the UK.
CONCLUSIONS: The inclusion of PROs in HTA is increasing in Europe. However, there are differences in the inclusion of PROs between European countries. These differences could be due to the differences in the methodology used in the HTA processes in each country.

23, HAS: 28; G-RA: 11; IQWIG: 13) covering 31 oncology drugs were reviewed. Thirteen (41%) of these drugs had >1 PRO claims in their European label; corresponding HTA submissions also included PROs. Manufacturers presented PROs in 67% (57/85) of HTA submissions (BC: 72.7%; NSCLC: 100%; PaC: 0%; PC: 77.3%; leukemias: 43.5%). PROs were also presented in the HTA submissions of 8 drugs with no EMA PRO data. In HTA submissions, PROs assessing PaC (0.17; 89.7%); 31.2% were the most common. Statistical significance was observed in 59.6% of the 52 submissions with available results. In the final HTA decision, PROs were mentioned for 13 (23%) of the submissions, not all were associated with PROs. PROs were not required by the HTA body in 21.0% of submissions due mainly to methodological issues. CONCLUSIONS: Demonstrating a statistically significant improvement in PROs does not necessarily affect the HTA recommendation. The value that PRO claims in oncology have to payers needs to be further clarified.

PCN22
DEVELOPMENT OF A PATIENT-REPORTED OUTCOME (PRO) ASSESSMENT OF CORE NON-SMALL CELL LUNG CANCER (NSCLC) SYMPTOMS
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1Evidera, Inc., Bethesda, MD, USA, 2Northwestern University Feinberg School of Medicine, Chicago, IL, USA, 3Eurepax, Basel, Switzerland
OBJECTIVES: Lung cancer is the leading cause of cancer-related mortality worldwide. Patients experience symptoms throughout the course of their disease which detrimentally affect their health-related quality of life (HRQoL). The assessment and monitoring of changes in NSCLC symptoms is increasingly important in clinical trials when making treatment comparisons between therapies. The objective was to develop a brief assessment of core symptoms that is applicable for use in both the clinical and clinical trials. METHODS: This non-interventional, cross-sectional qualitative study consisted of conducting individual interviews with NSCLC patients. Patients aged ≥ 18 years with diagnosed stage IB-IIIB NSCLC were recruited in 98 NSCLC centers in the US. Descriptions of NSCLC symptoms, including severity, frequency and change over time were collected. RESULTS: 17 treatment-naïve patients (mean age 63.8 years) were recruited for conducting and common symptoms of NSCLC patients were cited. Among the symptoms of NSCLC were cough (58.8%), shortness of breath (47.1%), chest pain (47.1%) and fatigue (29.4%). These symptoms were included in the initial 12-item version of the Symptoms In Lung Cancer (SILC) scale. An additional 10-post treatment patients aged ≥ 63.8 years participated in cognitive interviews to ensure that the items were correctly interpreted, relevant, and disease-related (i.e., not treatment-related). They overall found the SILC easy to complete and interpreted most of the items as intended. Items related to fatigue were removed as post treatment patients found these concepts difficult to attribute to their disease, and were reported by less than a third of treatment-naïve patients. The final 9-item SILC uses a 5-point verbal response scale (higher scores indicating greater severity/frequency/post treatment)–day recall period. Items assesses 3 core symptoms: chest pain (severity and frequency), cough (severity and frequency), dyspnea (while lying down/standing, walking, carrying a light load and when walking up an incline). CONCLUSIONS: SILC is an easy-to-use and concise tool to assess the core symptoms of disease in NSCLC patients.

PCN232
CANCER IS ASSOCIATED WITH INTRAOPERATIVE AND POSTSURGICAL COMPLICATIONS AND DISORDERS
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OBJECTIVES: The rate of nosocomial infections plays important role especially for patients with severe sickness and lengthy hospital stays. To better understand association between factors, real world evidence data from primary care patients was associated risk factors, real world evidence data from primary care patients was further clarified.
METHODS: This was a retrospective observational study of patients who had first diagnosis of intra- or postoperative complications (“IPC”). The European labels.
RESULTS: The risk of nocosomial infections plays important role especially for operations patients (mean age = 63.8 years) were recruited for conducting and common symptoms of NSCLC patients were cited. Among the symptoms of NSCLC were cough (58.8%), shortness of breath (47.1%), chest pain (47.1%) and fatigue (29.4%). These symptoms were included in the initial 12-item version of the Symptoms In Lung Cancer (SILC) scale. An additional 10-post treatment patients aged ≥ 63.8 years participated in cognitive interviews to ensure that the items were correctly interpreted, relevant, and disease-related (i.e., not treatment-related). They overall found the SILC easy to complete and interpreted most of the items as intended. Items related to fatigue were removed as post treatment patients found these concepts difficult to attribute to their disease, and were reported by less than a third of treatment-naïve patients. The final 9-item SILC uses a 5-point verbal response scale (higher scores indicating greater severity/frequency/post treatment)–day recall period. Items assesses 3 core symptoms: chest pain (severity and frequency), cough (severity and frequency), dyspnea (while lying down/standing, walking, carrying a light load and when walking up an incline). CONCLUSIONS: SILC is an easy-to-use and concise tool to assess the core symptoms of disease in NSCLC patients.

PCN233
DEVELOPMENT OF A PATIENT-REPORTED OUTCOME (PRO) ASSESSMENT OF CORE NON-SMALL CELL LUNG CANCER (NSCLC) SYMPTOMS
Debuusk K1, Johnson N2, Evans C3, Sandier K2, Ramalingam SS2, Campbell A1
1Evidera, Inc., Bethesda, MD, USA, 2Northwestern University Feinberg School of Medicine, Chicago, IL, USA, 3Eurepax, Basel, Switzerland
OBJECTIVES: Lung cancer is the leading cause of cancer-related mortality worldwide. Patients experience symptoms throughout the course of their disease which detrimentally affect their health-related quality of life (HRQoL). The assessment and monitoring of changes in NSCLC symptoms is increasingly important in clinical trials when making treatment comparisons between therapies. The objective was to develop a brief assessment of core symptoms that is applicable for use in both the clinical and clinical trials. METHODS: This non-interventional, cross-sectional qualitative study consisted of conducting individual interviews with NSCLC patients. Patients aged ≥ 18 years with diagnosed stage IB-IIIB NSCLC were recruited in 98 NSCLC centers in the US. Descriptions of NSCLC symptoms, including severity, frequency and change over time were collected. RESULTS: 17 treatment-naïve patients (mean age 63.8 years) were recruited for conducting and common symptoms of NSCLC patients were cited. Among the symptoms of NSCLC were cough (58.8%), shortness of breath (47.1%), chest pain (47.1%) and fatigue (29.4%). These symptoms were included in the initial 12-item version of the Symptoms In Lung Cancer (SILC) scale. An additional 10-post treatment patients aged ≥ 63.8 years participated in cognitive interviews to ensure that the items were correctly interpreted, relevant, and disease-related (i.e., not treatment-related). They overall found the SILC easy to complete and interpreted most of the items as intended. Items related to fatigue were removed as post treatment patients found these concepts difficult to attribute to their disease, and were reported by less than a third of treatment-naïve patients. The final 9-item SILC uses a 5-point verbal response scale (higher scores indicating greater severity/frequency/post treatment)–day recall period. Items assesses 3 core symptoms: chest pain (severity and frequency), cough (severity and frequency), dyspnea (while lying down/standing, walking, carrying a light load and when walking up an incline). CONCLUSIONS: SILC is an easy-to-use and concise tool to assess the core symptoms of disease in NSCLC patients.

PCN234
NOSOCOMIAL INFECTION AND LINGUISTIC VALIDATION OF THE MODIFIED MYELOPROLIFERATIVE NEOSPASM SYMPTOM ASSESSMENT FORM - TOTAL SYMPTOM SCORE (MMPN-SAT TSS) FOR USE IN 26 COUNTRIES
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OBJECTIVES: Symptom burden is critical for assessing therapeutic efficacy in myeloproliferation, characterized by splenomegaly, abdominal and constitutional mortality.

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