horizontal differentiation), which is often cited (beside R&D costs) as the second barrier to entry or break-even for biopharmaceutical companies. Here, we have discussed the regulatory model within various ATC groups and jurisdictions. We have also critically examined preponderance of “me-too” entries, particularly in the light of an R&D investment of the branded firms. Historically, “me-too” drugs are more ubiquitous than often realized. Their use precludes the patented solutions and adds to the global research community to contribute their intermediate results in exchange for access to the data contributed by others could rapidly gain momentum. Such a system would challenge data protectionism by identifying the disease area and level of innovation required for price assessment that would not only contribute to optimization of societal wealth but width also in the long run increase an R&D productivity of branded firms.

PHP230
CELL THERAPIES: ASSESSING THE PATIENT ACCESS OPPORTUNITIES AND CHALLENGES THAT LIE AHEAD
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This poster seeks to highlight the key challenges and opportunities surrounding patient access to innovative cell therapies in the EU and US. The findings are based on second-order sources, patient interviews, and payer focus groups that considered patients in the EU and US. Cell therapies have a unique opportunity to improve patient outcomes but face their own set of challenges due to being cell-based. As many of these therapies involve manipulation of the patients’ own cells before being reintroduced (e.g., ChondroCelect), the associated side effects are likely to be minimal. Other therapies (e.g., gene therapy, Cypher) involve the introduction of foreign genetic material but provide a potential long-term cure. However, there are some important challenges that need to be addressed when considering how to commercialize such therapies. In the case of therapies where a patient’s cells are manipulated ex vivo, who bears the risk if the patient does not receive their individualized treatment? For those therapies that purport to cure disease, how much are healthcare curative settings willing to pay for them and what evidence would be required in order to justify a high price? Moreover, for all therapies, there is the uncertainty regarding access pathways: will cell therapies necessarily undergo an HTA evaluation before gaining access to the EU? What are the potential implications of whether such a therapy is deemed a product (and, hence, undergo an assessment like a regulatory biopharmaceutical) or a procedure (and likely bypass a national evaluation)? In conclusion, cell therapies face uncertainties in market access and funding due to uncertainty in payers’ perception of the spectrum of claims that can be attributed to cell therapy umbrella. Until frameworks have been put in place, each cell therapy should be assessed individually in order to determine likely pathway to patient access.

PHP231
THE IMPACT OF RECENT GENERIC DRUG PRICE POLICIES ON PHARMACEUTICAL INNOVATION: A THEORETICAL RATIONALE AND PROPOSAL OF A METHOD SUPPORTING INSIGHTS IN AREAS OF UNMET MEDICAL NEED
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New discoveries are a critical priority for the pharmaceutical industry, for which the primary aim should be to address unmet medical needs. However, the use of fixed cost-effectiveness (ICER) thresholds for health technology assessment (HTA) may tend to decrease incentives to innovate and affect future treatment options. This paper attempts to address this issue, using a case study on how such measures may impact key drivers for pharmaceutical innovation in the context of fixed ICER thresholds and proposes a new consideration for the cost-effectiveness analysis (CEA). There is a growing relationship between HTA and the market price of a drug, in jurisdictions where HTA agencies apply fixed ICER thresholds as an important reimbursement listing criterion, the incremental cost of a new drug is expected to be proportional to its incremental benefit over the comparator. However, the comparator price for a patented drug is also subject to market factors. A price that may change depending on the cost-effectiveness assessment (e.g., where the comparator patent has expired). Since recent generic price regulations (e.g. 18% or 25% of the innovative price in Canada) increase the relative gap between drugs’ generic and patented versions, it is harder to achieve a sufficient level of incremental benefits in order to offset incremental prices of new treatments. This analysis thus demonstrates that with recent changes in generic drug prices in Canada and other jurisdictions, even promising drugs will have challenges to show attractive ICERs. Traditional decision-making process should be adapted to reflect these changes and to promote innovation in therapeutic fields with unmet medical needs. A compromise would be to include the comparator’s patented price in the calculation instead of the generic price in certain areas of unmet needs. By identifying the relevant disease areas, decision makers and HTA authorities could convey the importance of investing in these therapeutic areas to manufacturers.

PHP232
THREE-BALANCED SCOPING OF COMPARATIVE EFFECTIVENESS RESEARCH REVIEWS: COLLATERAL INFORMATION SYSTEMS SOLUTIONS
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Backbone for pharmacoeconomic research in general and systematic reviews is rapidly expanding due to increasing demand for more complex models that account for patient, treatment, and trial characteristics, network meta-analyses that include more complex comparison networks, healthcare systems, and jurisdictions. By the year 2000, the effort required to publish a typical systematic review had already reached the thousands of person-hours, which were predominantly spent on data acquisition tasks. Innovative solutions are required to prevent the costs of comparative effectiveness research from ballooning out of proportion. PROBLEM: Typically only the end product of systematic reviewing, a report summarizing the evidence, is made widely available. However, capturing the intermediate results of literature searching, publication screening, and data and thereby has the potential to greatly enhance the efficiency of future reviewing. In the face of the increasing scope of systematic reviews, this unnessary duplication of effort must be eliminated. However, doing so is difficult due to the requirements of data storage and a lack of suitable software that enables convenient and useful sharing of the intermediate results. APPROACH: Building on our previously published reviews of software for systematic review and trial analysis, the talk identifies the technical and cultural challenges to be met. We propose that by identifying the level of exercising the VBP HTA methodology itself could be more conservative than the current approach. Protracted negotiation may also delay access in Scotland and Northern Ireland. Equally, manufacturers may postpone launch in the UK if they consider VBP a threat in their price corridor in other markets. Finally, it is not clear if additional regional or local level negotiations will take place in this price corridor, the benchmark price of which could further delay access in conclusion, although there is potential for the new adjustable QALY threshold (which remains to be confirmed) to foster innovation, the ability of the new VBP process to expedite patient access remains uncertain.

PHP233
VALUE-BASED PRICING IN THE UK AND POTENTIAL PATIENT ACCESS HURDLES TO INNOVATIVE DRUGS
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The UK government plans to introduce value-based pricing (VBP) for medicines in England and Wales from January 2014, and one of the key tenets of the scheme is to improve patient access to new innovative drugs. This poster aims to explore the extent to which VBP is likely to achieve this goal. To meet this objective, an in-depth review of available literature (including white papers from key stakeholders and scientific publications) was conducted. Targeted interviews with five leading thought-leaders in the implementation of VBP were also conducted to support analysis. Research identified a number of uncertainties in VBP implementation that could detrimentally impact patient access to new drugs. First, the timeline for the VBP negotiation process remains unclear. Currently, it takes NICE on average 48 weeks to issue guidance on a single technology appraisal, which could be extended if a technology is deemed not to be cost-effective. Under VBP, manufacturers will still be required to negotiate their price with the Department of Health if the calculated VBP price by NICE is unfavorable, and the VBP HTA methodology itself could be more conservative than the current approach. Protracted negotiation may also delay access in Scotland and Northern Ireland. Equally, manufacturers may postpone launch in the UK if they consider VBP a threat in their price corridor in other markets. Finally, it is not clear if additional regional or local level negotiations will take place in this price corridor, the benchmark price of which could further delay access in conclusion, although there is potential for the new adjustable QALY threshold (which remains to be confirmed) to foster innovation, the ability of the new VBP process to expedite patient access remains uncertain.

PHP235
A CHOICE OF BUSINESS FOR THE PHARMACEUTICAL INDUSTRY “SEGURO POPULAR” IN MEXICO
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A choice of business for the pharmaceutical industry “Seguro Popular” in Mexico. Abstract. Mexico has various providers of health services each one determined to a sector of the population where we can find the Mexican Social Security Institute (IMSS) that is specifically for workers in the private sector employees and their families, the Institute for security and services social of the State workers (ISSSTE) for workers in the service of the State or public sector and their families starting 2003 ushered to the Seguro Popular that extends to the population without social security. There are three main differences between IMSS and ISSSTE, the first is energizing as institutions providing health services larger Mexico insonmuch that by 2013 the Seguro Popular has approximately 54 million affiliates number of successful membership in less than 10 years in a country where there is little more than 110 million people. While Seguro Popular is the largest buyer of drugs, aware of this are his consumption figures that since 2008 has been made public, in such data can find that from 2008 to 2012 they have bought 1,241,637,748.68 US Dlls only in drugs consumption regularly since the Seguro Popular has several portfolios of services where separate regular conditions of low frequency and high cost and conditions of very low frequency and high cost for children under 5 years who in turn have specific budgets.

DISEASE-SPECIFIC STUDIES
GASTROINTESTINAL DISORDERS – Clinical Outcomes Studies
PG1
UNDERSTANDING THE EFFECT OF CLOSTRIDIUM DIFFICILE INFECTION ON HOSPITAL MORTALITY IN ENGLAND, THE NETHERLANDS, AND SPAIN
Wasserman M.1, Jones C.1, Roberts G.1, Latif F.2
OBJECTIVES: Increasing rates of Clostridium Difficile Infection (CDI), a hospital-acquired infection, has stimulated a number of financial incentives and government sponsored initiatives to quell the spread of the disease. Previous research has shown the importance of hospital-onset CDI on extending the hospital length of stay (HLOS) and adding to hospital mortality. The purpose of this study is to evaluate the impact of CDI on in-hospital mortality. METHODS: Data were obtained from national hospital episode datasets in the United Kingdom, The Netherlands, and Spain. Only CDI cases of patients aged 50 and above, those diagnosed with chronic kidney disease, heart failure, and chronic obstructive pulmonary disease (COPD) were included in the analysis. Cases of CDI were stratified between hospital-onset and community-onset cases. Only those that were assumed to be hospital-onset were included in the analysis. A logistical regression was used to predict the relative effect hospital-onset CDI had on in-hospital mortality. A number of covariates were controlled for including: age, sex, comorbidities, and length of stay in hospital. Results: Patients with hospital-onset CDI had an overall higher mortality rate compared to those who...