Science, pharmaceutical formulation and analytics, supply vendors, analytical testing laboratories, and product testing laboratories. Present the information using a user friendly format including flow charts and development timelines, taking the perspective of the translational investigator. RESULTS/ANTICIPATED RESULTS:

- Choosing AMC resources vs outside consultants and vendors, leveraging local resources where possible
- Qualifying and monitoring suppliers, testing laboratories, in-house departments, and Contract Drug Manufacturing Organizations (CDMO)
- Bringing together the deliverables for the IND CMC section
- Where and how to leverage available products and science to simplify safe and reliable production

DISCUSSION/SIGNIFICANCE OF IMPACT: Use and utility of injectable drug products, both small molecule and biologics, is growing rapidly, and is projected to continue to escalate well into the next decade. This is due not only to advances in medicine, but also to improvements in AMC-based sterile product production, and a better understanding of small batch manufacturing methods. All three trends align in academic medical centers (AMC) and can be utilized by translational researchers, if they can understand the potential and regulatory requirements.

**Data Science/Biostatistics/Informatics**

**4391**

**Big data analysis of adolescent obesity, pregnancy and kidney function**

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OBJECTIVES/GOALS: 1. Examine the associations among BMI and markers of cardiometabolic risk, including blood pressure, lipids and blood glucose.
2. Assess prevalence of kidney function deterioration, identified as hyperfiltration and moderately increased albuminuria (MIA), in obese compared to normal weight adolescents.

METHODS/STUDY POPULATION: De-identified electronic health records (EHR) data were extracted for female adolescents, aged 12-21 years, and their offspring through 24 months, who received health care services (Jan 2012 to Dec 2016) in NYC from 12 academic health centers and community health centers that are part of PCORnet NYC Clinical Data Research Network (NYC-CDRN). Data were analyzed using SAS (version 3.2.5). Patient characteristics overall and for study subgroups were examined using standard summary statistics. Trends in cardio-renal variables were examined by BMI groups coded according to NHANES as underweight, normal weight, overweight or obese. Multiple linear regression analyses will control for covariates. RESULTS/ANTICIPATED RESULTS: Data from 651,066 adolescent females ages 12-21 were retrieved. Analysis was performed on a subset of 202,214 unique patients (26% white, 15% black, 12.9% Latina) for whom there was complete data for BMI and blood pressure. Distribution of BMI was 6% underweight, 59% normal weight, 19% overweight, and 17% obese. There were significant differences in mean systolic (SBP, mean ± SD mmHg: 102 ± 12, 108 ± 11, 112 ± 12, 116 ± 12) and diastolic blood pressure (DBP, mean ± SD mmHg: 62 ± 10, 66 ± 8, 68 ± 8.9, 70 ± 9) across the four BMI groups with an increasing trend (p-values < 0.0001). We will examine renal function trends, and whether these cardio-renal differences persist when controlling for age, race and ethnicity. DISCUSSION/SIGNIFICANCE OF IMPACT: Although SBP/DBP means were within normal limits across BMI groups, significant increasing trends suggest that women in higher BMI groups may be at increased risk for hypertension and potentially for renal dysfunction. We will examine contributions of race/ethnicity and age to these associations.