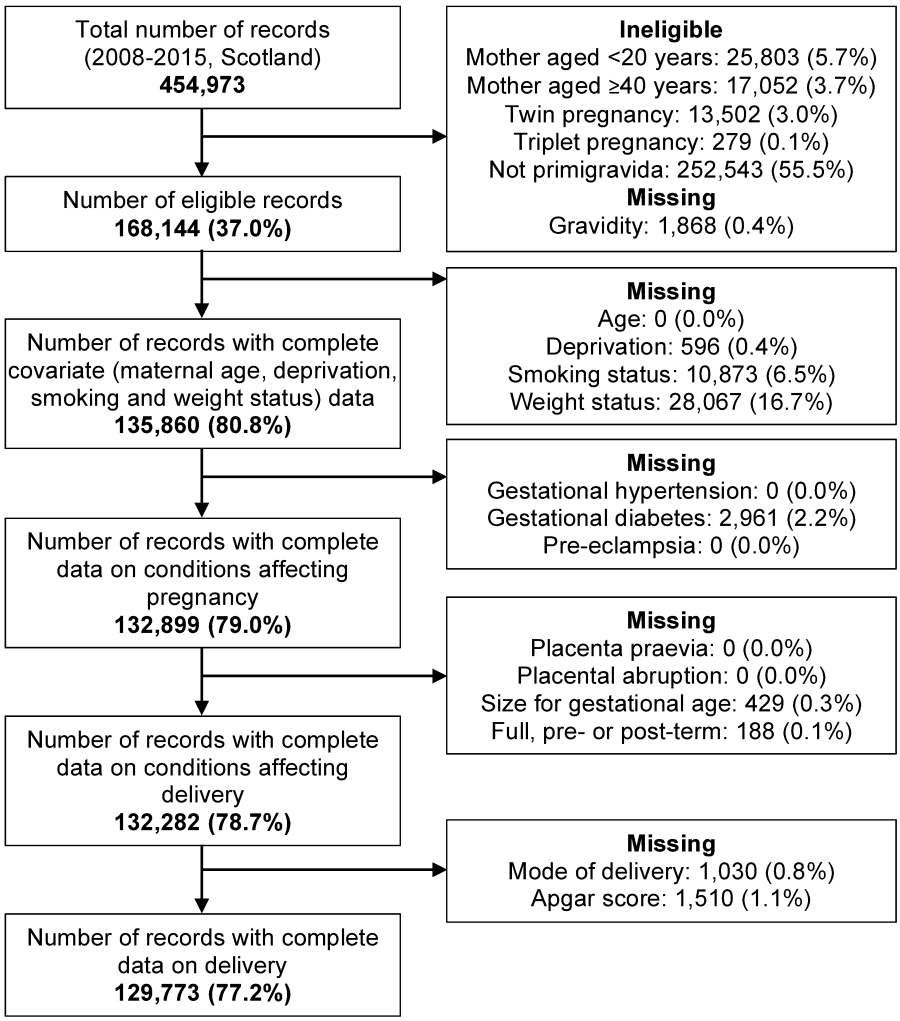Supplementary file 2. Study flow diagram