In France, patients can benefit an early access to innovation, ahead of the marketing authorization or final reimbursement since 1992. This early access program (EAP) was reformed on July 1, 2021. As of this date, the eligibility criteria, the agency responsible for EAP granting, the timelines and the process have evolved. Medicines indicated in a severe, rare or disabling disease, are eligible to EAP when there is no suitable treatment available on the market, when efficacy and safety are presumed and when the product is considered presumed innovative.

**OBJECTIVES**

Our study consisted of a descriptive analysis of EAP first evaluations.

**RESULTS**

- Among 46 EAP decisions published, 37% concerned medicines without marketing authorization (MA) and 63% concerned medicines with a MA.
- The most represented therapeutic area was oncology (46%) and 17% decisions were related to COVID-19 therapies.

**CONCLUSION**

Since the reform, evaluation for EAP is conducted according to TC requirements and became a very important preparatory step for reimbursement. Pharmaceutical companies must ensure consistency between EAP and reimbursement dossiers and think about their market access strategy at a much earlier stage.