Using the Britest approach for the redesign of an API manufacturing process

Challenge & Approach

- Existing expensive **6 step manufacturing process** to API with **4 isolations** (one a chiral **resolution step**).
- **Long lead time** from Regulatory Starting Material to API.
- **Need to reduce cost, increase throughput** and **reduce process footprint**.
- Unprecedented chemistry developed as 2nd generation process .

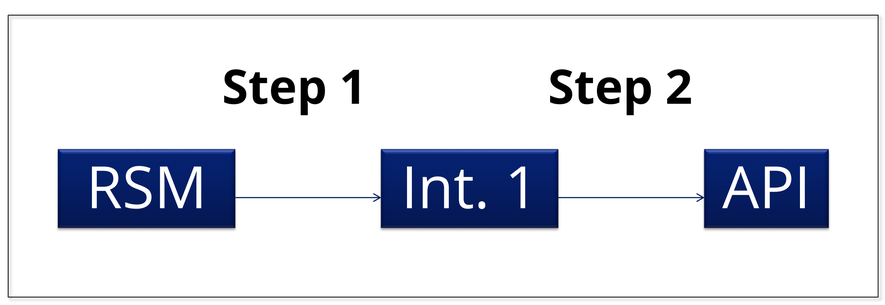
➔Optimisation of the new process using a structured approach;

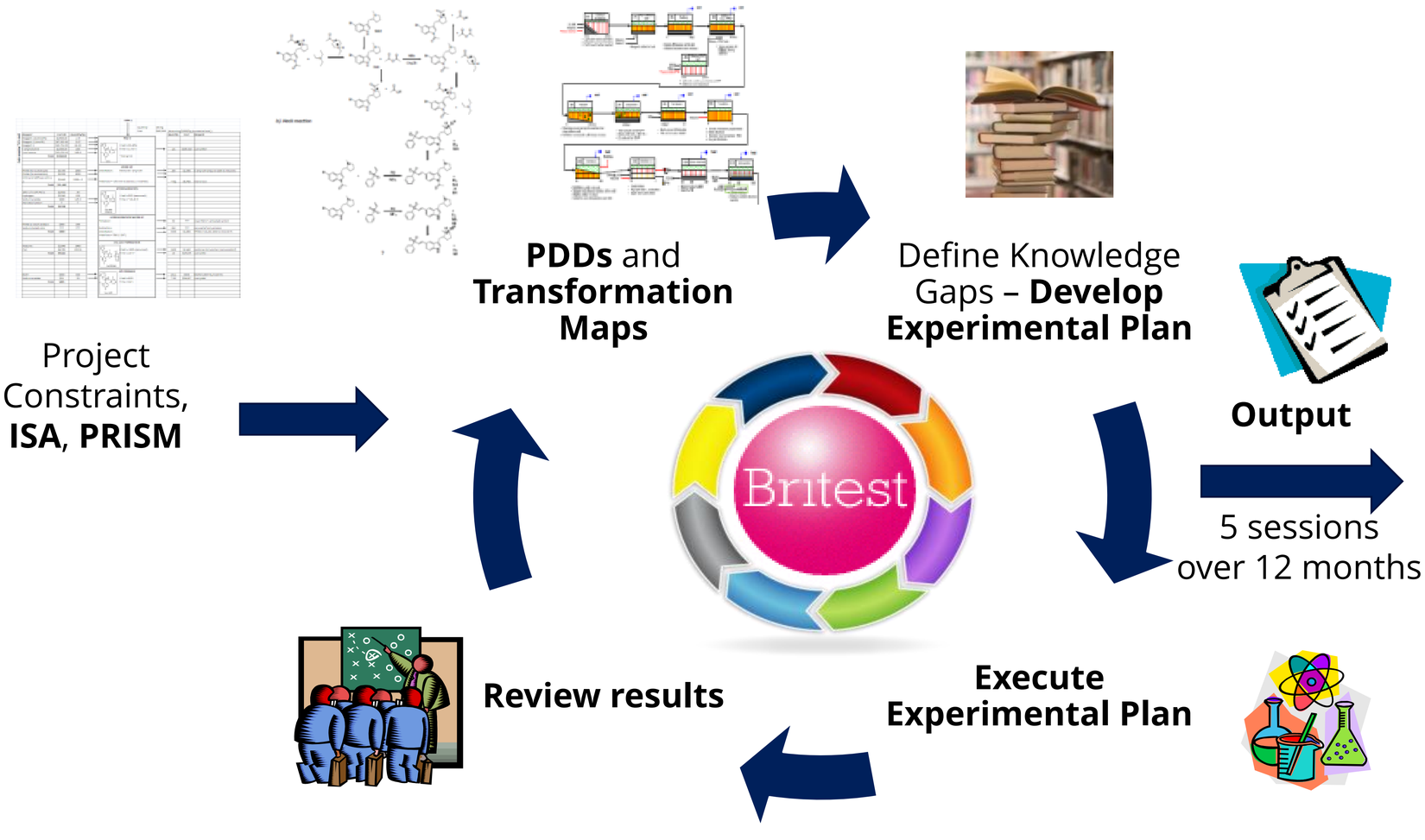
➔Transfer new process to receiving site.

Britest **Key to success**

Redesigned Process:

- **Two step process** (versus 6 step 1st gen process).
- Route is both diastereo and enantio selective.
- **But yield improvement required to reduce cost**.





Focus areas:

- Reduced loading
- Chemoselectivity
- Improved quality
- Yield/Cost

Solution & Benefits:

- **Yield improved** through **increased process knowledge**.
- Development of well understood **scaleable process**.
- Implementation leading to cost savings of **>50% reduction in API cost**.
- Improved **knowledge transfer to receiving site**.
- Repeat use of BRITEST tools with colleagues from other sites to develop familiarity & good practice.
- Patent application filed.

Supporting organisations in gaining value from process understanding