[F-18]FLT: (3'-deoxy-3'-[F-18]fluorothymidine):

FREQUENTLY ASKED QUESTIONS

What is the status of FLT at the Cancer Imaging Program?

We have an established IND (11/2004) for FLT that we actively encourage investigators to cross-file on

- We freely provide manufacturing and quality control documentation to assist this effort. https://imaging.cancer.gov/programs_resources/IND_regulatory_manufacturing.htm
- We have Letters of Authorization in our IND to the Drug Master Files (DMF) from two of the commercial FDG suppliers who can provide FLT.
- We encourage academic and pharmaceutical investigators to evaluate FLT for therapeutic drug evaluation/development, diagnosis, or response to treatment.
- We anticipate that the data resulting from wider availability of this agent will support an eventual New Drug Application (NDA) by a commercial entity.

What is the Regulatory Status of FLT?

FLT is an investigational PET agent. Several individuals and organizations hold an Investigational New Drug (IND) Exemption from the FDA under which they are permitted to make and use FLT. IND information can be found here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-new-drug-applications-positron-emission-tomography-pet-drugs

How can I use FLT in my clinical trial?

In order to use FLT, you must hold an IND or have your basic science trial approved by your Institution's RDRC (Radioactive Drug Research Committee). In either case, you must have your trial approved by an Institutional Review Board (IRB).

Can I make my own FLT?

If you have appropriate facilities (cyclotron, radiochemistry lab and personnel, capacity to manufacture PET agents for human use), you can make FLT. Your chemistry procedures must be acceptable to FDA for your IND or to the RDRC, and to the IRB.

Can I buy FLT from someone to use in my trial?

Some commercial firms do provide FLT for research use. That material can be used in your clinical trial only if you submit appropriate chemistry information to FDA in your IND. At this time, to the best of our knowledge, two of these companies have a Drug Master File (DMF) on file with the FDA for this agent, which will permit use of this material in your IND-approved trial if the company provides you with an appropriate authorization letter or if you have a letter of authorization to our IND, which contains appropriate authorizations.

How can NCI help?

NCI can assist in two ways. NCI holds an IND for FLT that is based on a specific automated synthesis performed on a nucleophilic substitution box. Documents necessary to prepare and test FLT for use in clinical trials are available on the Cancer Imaging Program (CIP) website. https://imaging.cancer.gov/programs_resources/IND_regulatory_manufacturing.htm

The documents include a full set of manufacturing and QC documents ("SOPs") and an Investigator Drug Brochure, all of which have been accepted by the FDA as part of the NCI IND. The synthetic method is after Machulla H.J. et al. Procedure for Routine Synthesis of [18F] FLT in High Activities. J. Nucl. Med; 42 (5), 257P, 2001. Investigators at each site can implement this synthesis and testing in their radiochemistry laboratory. There is a CMC template that may need to be modified to match the local procedures (e.g. specific brands of equipment). Investigators can then write and file their own IND with the FDA by modifying the CMC section to fit local conditions and adding the Investigator's proposed Clinical protocol.

Additionally, CIP will provide a Letter of Authorization (cross-file letter) to the FDA in conjunction with your IND that can simplify your IND application. This letter may substitute for the Pharmacology, Toxicology, Radiation Dosimetry and Previous Human Experience sections of the IND.

If you do purchase FLT from a company that holds a DMF, their Letter of Authorization will substitute for the Chemistry, Manufacturing, and Control section of your IND.

For additional information

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