



## Hyperpolarized Pyruvate (13C) Injection

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#### **What is the status of Hyperpolarized Pyruvate (13C) Injection at the Cancer Imaging Program?**

We have an established IND (ownership transferred from GE in 2015) for Hyperpolarized Pyruvate (13C) Injection that we actively encourage investigators to cross-file on

- We freely provide some [documentation](#) to assist this effort
- We encourage academic and pharmaceutical investigators to evaluate Hyperpolarized Pyruvate (13C) Injection for metabolic studies, including tumor biology and therapy response
- We anticipate that the data resulting from wider availability of this agent may support an eventual New Drug Application (NDA) by a commercial entity

#### **What is the Regulatory Status of Hyperpolarized Pyruvate (13C) Injection?**

Hyperpolarized Pyruvate (13C) Injection is an investigational MR agent. Individuals and organizations may apply for and hold an Investigational New Drug (IND) Exemption from the FDA under which they are permitted to make and use Hyperpolarized Pyruvate (13C) Injection. IND information can be found [here](#). Investigators not in the US need to comply with their local regulatory requirements

#### **How can I use Hyperpolarized Pyruvate (13C) Injection in my clinical trial?**

In order to use Hyperpolarized Pyruvate (13C) Injection in the US, you must hold an IND and have your trial approved by an Institutional Review Board (IRB); in other countries, investigators will

need to comply with the equivalent regulatory bodies in your country.

### **Can I make my own Hyperpolarized Pyruvate (13C) Injection?**

You must make your own Hyperpolarized Pyruvate (13C) Injection. Because of the very short half-life, Hyperpolarized Pyruvate (13C) Injection must be prepared on site in close proximity to your MR unit. Your chemistry procedures for Hyperpolarized Pyruvate (13C) Injection and the Hyperpolarized Pyruvate (13C) Drug Product Kit must be acceptable to your regulatory agency, such as the FDA and to your IRB or ethics committee.

### **Can I buy Hyperpolarized Pyruvate (13C) Injection from someone to use in my trial?**

No. You need to source the GMP/GLP reagents, equipment and supplies required to prepare the Hyperpolarized Pyruvate (13C) Injection and the Hyperpolarized Pyruvate (13C) Drug Product Kit. The hyperpolarization step must be performed on site in close proximity to your MR unit

### **How can NCI help?**

NCI holds an IND for Hyperpolarized Pyruvate (13C) Injection originally filed by GE and transferred to the NCI. For investigators in the US, the NCI can provide a letter of reference to the IND that will incorporate the pharmacology, toxicology and previous human information in the original IND so it will not be necessary (nor advised) to file the actual information in those sections. For investigators outside the US, a list of the complete studies and a summary of the results are posted and the ones appropriate to your planned research can be requested for regulatory purposes. [Some documents are available on the Cancer Imaging Program \(CIP\) website.](#)

Investigators at each site in the US must implement the hyperpolarization then write and file their own IND with the FDA by providing a CMC section and adding the Investigator's proposed Clinical protocol. Sites outside the US must follow their national regulatory process.

### **For additional information**

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