

# CIRCLE DATASETS

## FOR PHYSICIANS WITH INSTITUTIONAL AFFILIATIONS

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### Introduction

Many physicians are interested in becoming Circle Members, but are unsure how to do so in the context of hospital system or other provider group (medical institution) affiliations. RegenMed stands ready to assist.

The clinical and financial benefits of Circle Datasets are substantial for virtually any medical institution. Analogous initiatives by [Duke Health](#) and [Mayo Clinic](#) are instructive. So too is the recent [discussion](#) by the FDA Commissioner regarding the importance of fit-for-purpose and high quality real world evidence developed in medical institutions regardless of type or size.

### Decision-Making

In view of the substantial financial and clinical benefits accruing for a medical institution, multiple decision-makers are likely to be involved in the development of a Circle Dataset program. These can include department chairs, research heads, and/or C-suite officers. Relevant MSO and/or private equity personnel may also wish to be involved.

### BAAs, DUTAs

RegenMed and the medical institution will typically execute a Business Associate Agreement covering compliance with HIPAA and other regulatory requirements. They will also execute a Data Use and Transfer Agreement. This will reflect, among other things, the terms desired by the medical institution with respect to federated Circle Dataset participation, discussed below.

### IRBs

The generation of Circle Datasets is not intended to involve human subjects research as defined under 45 CFR 46.102. See [here](#). However, RegenMed can work with commercial or academic IRBs to obtain an exemption or NHR designation. Similarly, if the medical institution wishes to use the Circle Platform for a research study, RegenMed can work with the investigators and assigned IRB to support the project.

### Federated Control and Participation

The patented Circle Platform is an integrated, turnkey and closed system. It enables unambiguous ownership of and control over resulting Circle Datasets. This, coupled with the high-quality of those Datasets is the foundation of their substantial clinical and financial value, and therefore intellectual property rights. See [here](#) and [here](#).

A medical institution can license the Circle Platform for use within its firewalls, or access it as a cloud-based solution. In either scenario, the medical institution maintains control over the use of its local data. As and when it wishes to benefit from the combination of its own Circle Datasets with external Circle Datasets, it can choose to do so.

## System Interoperability

RegenMed strongly recommends the maintenance of all Circle-based data within its closed system. This ensures unambiguous ownership and resulting high-value intellectual property rights. However, the Circle Platform incorporates FHIR-mapping, and can work efficiently with a medical institution to support interoperability with other healthcare data systems.

## Clinician Buy-In

The Circles Platform tracks real world data contributions on the basis of individual clinicians, and individual Observational Protocols. This gives a medical institution a high degree of flexibility in allocating Circle Dataset royalties to participating physicians. Together with its excellent clinician and patient UX, the Circle Platform is designed to maximize clinician buy-in for real-world initiatives in any therapeutic area.

## Phased Roll-Out

The low-cost and turnkey nature of the Circle Platform allows a small controlled pilot, to be scaled only after meeting pre-agreed KPI's.

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