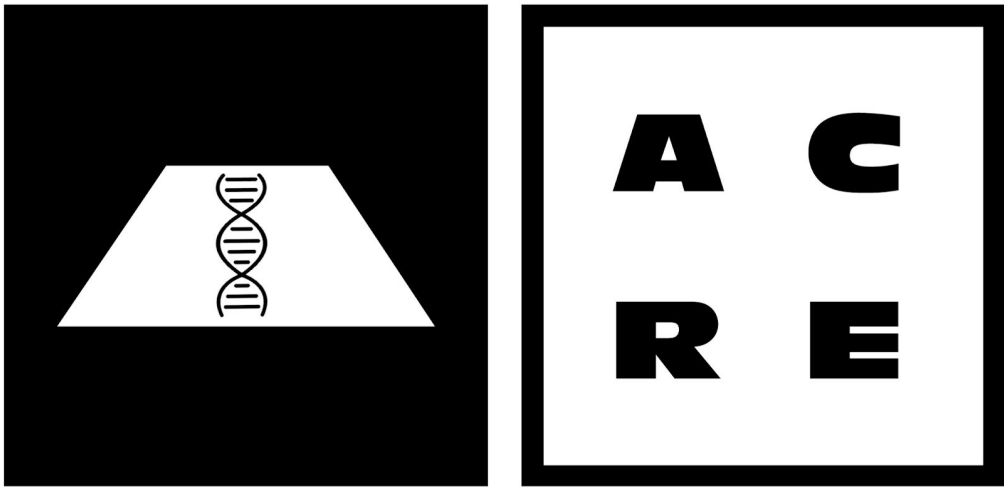

Project GAIA, Stage 1

[redacted]

-K. Shall, Director of [redacted]

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Overview

Over the years, biotechnological developments have allowed A.C.R.E scientists to alter the genetic make-up of [redacted]. Initially, these modifications have served the purpose of [redacted], but these techniques quickly became promising tools from an agricultural point of view since they allow the addition of novel traits to organisms which may increase their suitability for use in [redacted]

With this new project we intend to take our research [redacted] techniques not just on [redacted], but on the [redacted]. These modifications [redacted] These are just a few examples of what we at A.C.R.E. could do.

Goals

1. Safely and securely begin the testing and [redacted] of [redacted]
2. Troubleshoot and ensure [redacted]
3. Put into place a [redacted] plan including clinical trials.

Specifications

Figure 1 Has outlined a few of the [redacted] use in the upcoming projects on [redacted].

Species	Category	ID	Transgene	Origin	Effect/Goal
[redacted]	[redacted]	1	[redacted]	[redacted]	Disease Resistance
		2	[redacted]	[redacted]	Disease Resistance
		3	[redacted]	[redacted]	General Health
[redacted]	[redacted]	4	[redacted]	[redacted]	General Health
[redacted]	[redacted]	5	[redacted]	Piscine	Growth Rate
		6	[redacted]	[redacted]	Disease Resistance
[redacted]	[redacted]	7	[redacted]	[redacted]	Disease Resistance
	[redacted]	8	[redacted]	Human-[redacted]	General Health
		9	[redacted]	Human-[redacted]	Anti clotting agent
[redacted]	[redacted]	10	[redacted]	E. Coli-[redacted]	Feed uptake
		11	[redacted]	Human-[redacted]	Growth rate
		12	[redacted]	[redacted]	Muscle development

Figure 1.

Outline of Clinical Trials

Four phases of clinical trials and medicine development exist and are defined below. Each of these definitions is a functional one and the terms are not defined on a strict chronological basis. An investigational medicine is often evaluated in two or more phases simultaneously in different clinical trials. Also, some clinical trials may overlap two different phases.

Phase I: Initial safety trials on the [redacted]. An attempt is made [redacted] volunteers for [redacted]. Phase I trials are sometimes conducted [redacted] when pharmacokinetic issues [redacted]. Pharmacokinetic trials are usually considered Phase I trials regardless of when they are conducted during [redacted] development.

Phase IIa: Pilot clinical trials to evaluate [redacted] in selected populations [redacted] we deem worthy. Objectives may focus [redacted] numerous other characteristics of [redacted].

Phase IIb: Well controlled trials to [redacted]. These clinical trials usually represent the most rigorous [redacted].

Phase IIIa: Trials conducted after [redacted] submission of a [redacted] or other dossier. These clinical trials are conducted [redacted] eventually intended. Phase IIIa clinical trials generate additional data on both [redacted] in relatively large numbers [redacted] in both [redacted]. Clinical trials are also conducted in special groups [redacted], or under special conditions. These trials often provide much of the information needed for [redacted].

Phase IIIb: Clinical trials conducted [redacted], but prior to [redacted] launch. These trials may supplement earlier trials, complete earlier trials, or may be directed toward new types of trials [redacted] or Phase IV evaluations. This is the period between submission and approval [redacted]

Phase IV: Studies or trials conducted after the [redacted] can be studied. [redacted]

Milestones

As laid out above in the [redacted] Below is the timeline of Milestones in which we wish to hit.

Milestone 1: [redacted]- Time: [redacted]

Research and development usually takes anywhere from [redacted]. We of the [redacted] have been using theses methods [redacted] proper procedures and have expedited the process down to a [redacted] progress into the next phase of the trial.

Milestone 2: [redacted]. Time: [redacted]

Phase 1 can begin [redacted]. The first trial consists of a test group of between [redacted] individuals and each trial will run [redacted].

Milestone 3: [redacted]. Time: [redacted]

Phase 2 will consist [redacted] individuals at a time who will be participating in the program for [redacted]. We will continue to monitor [redacted]. We will use this time to [redacted]

Milestone 4: [redacted].Time: [redacted]

Phase 3 will test [redacted] at a time. During this phase we will [redacted]. This phase will run for [redacted]

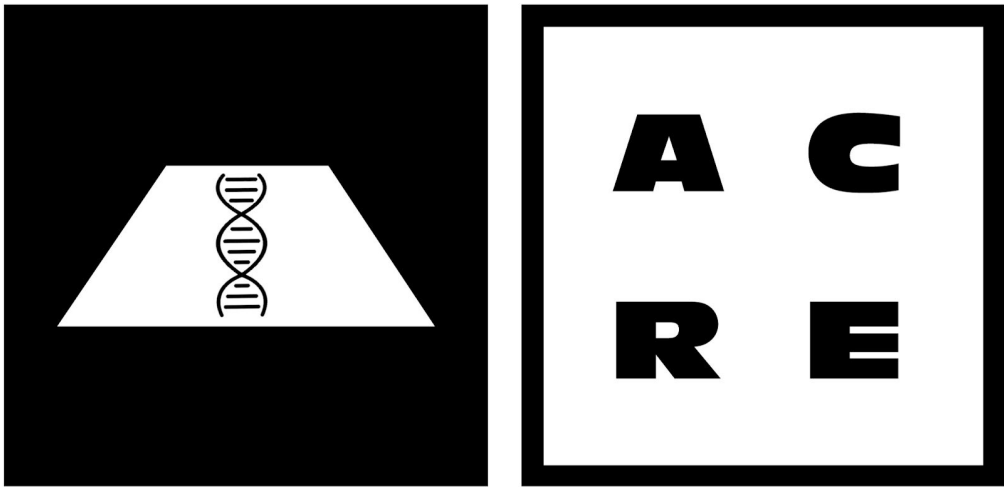
Milestone 5: [redacted] Time- [redacted]

The "[redacted]" is one of [redacted]. Seeing [redacted]. By this point [redacted]. It was suggested to [redacted]

Below is Figure 2 which is a flowchart of the proposed Project GAIA.

[redacted]

[redacted]



Project GAIA, Stage 2

[redacted]

-K. Shall, Director of [redacted]

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