AgbioInvestor

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THE QUEEN'S AWARDS FOR ENTERPRISE: INTERNATIONAL TRADE 2022

Time and Cost to Develop a New GM Trait

RESULTS APRIL 2022

Cost and Time Required for the Discovery, Development and Authorisation of a New Plant Biotechnology-Derived Genetic Trait

A Study on Behalf of Crop Life International

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Executive Summary

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Executive Summary

Rationale

- To provide an up-to-date view on the cost and duration of the discovery, development and authorisation of a new plant biotechnology-derived trait that has received cultivation approval in at least two countries and import approvals from at least five countries.
- The data to be collected was intended to demonstrate the current situation according to three main categories:
  - Cost of each part of the discovery, development and authorisation process.
  - Time involved to complete each part of the process needed to commercialise a biotechnology-derived genetic trait.
  - Total consecutive time required to bring a biotechnology-derived genetic trait from discovery to commercialisation (including authorisations).
- The aim of the study was to focus on a single novel trait and exclude the time and cost to develop and gain authorisation for stacked genetic traits containing multiple genetic events.

Method

- The data was collected via a questionnaire.
- The companies taking part were:
  - Bayer Crop Science
  - Corteva Agriscience
  - Syngenta
  - BASF Agricultural Solutions
- Responses were anonymised and compiled, with data averaged to produce a mean value for each activity stage.

Executive Summary Continued

Findings

- The cost of discovery, development and authorisation of a new plant biotechnology-derived genetic trait commercialised in the period from 2017 to 2022 is $115.0 million.
- The discovery phase of the process accounted for 6.6% of total costs and 13.3% of the non-consecutive total time.
- The genetic event construction and testing phase represented 55.8% of total costs and 35.6% of the non-consecutive total time.
- The regulatory phase, the longest duration of the overall process, accounted for 37.6% of total costs and 51.1% of the non-consecutive total time.
- The mean duration to bring a genetic trait to the point of commercialisation in 2017–2022 was 16.5 years. However, this study did not assess the time required to develop stacked trait varieties, which commonly represent commercial seed product offerings.
- As indicated by a comparison with the previous study, the cost of discovery, development and authorisation of a new plant biotechnology-derived genetic trait has declined from $136 million in the 2008–2012 period to the current value of $115 million, whilst the time required to complete the process has increased from 13.1 years to 16.5 years.

Introduction

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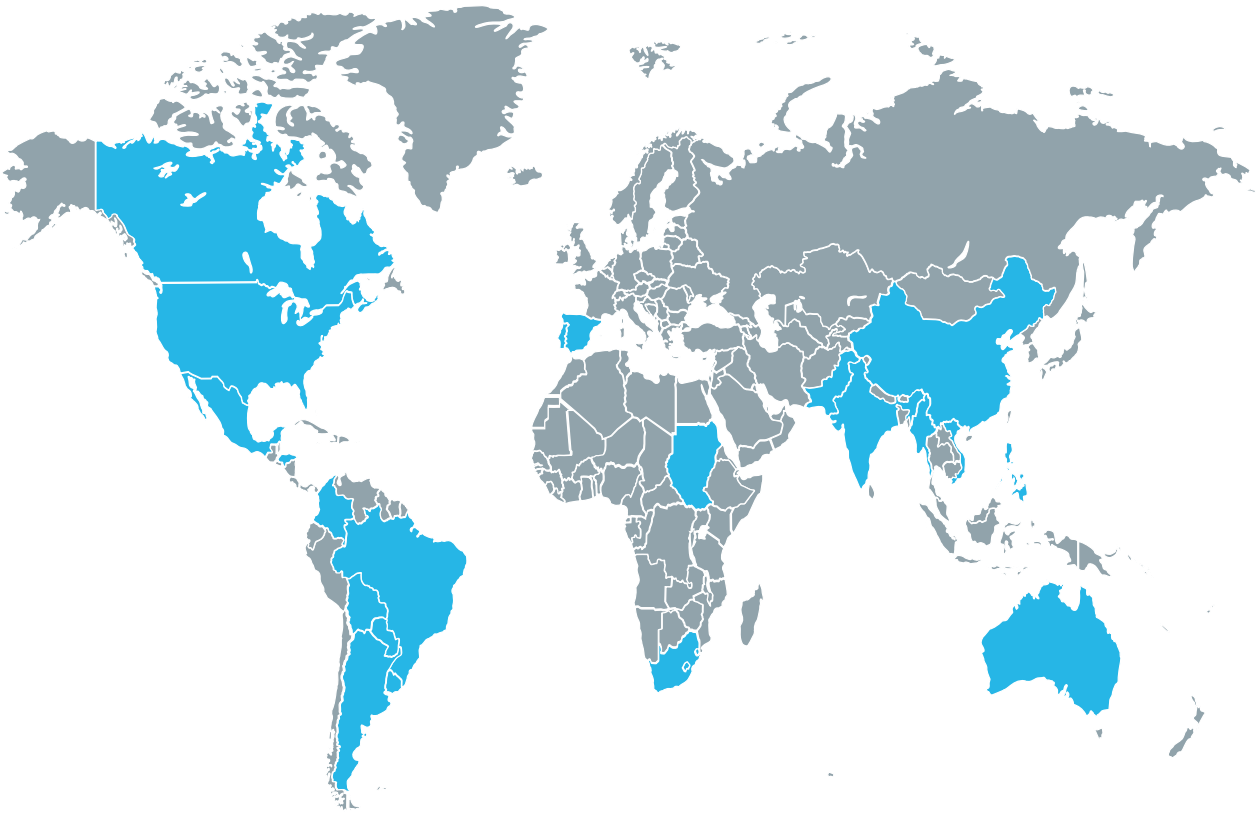
The first instance of a biotechnology-derived genetic trait in commercial agriculture was in 1995. Since then, the number of GM traits used in crops has increased significantly, which in turn has increased the level of technification, as well as the number of crop species and geographic spread.

Introduction

The first instance of a biotechnology-derived genetic trait in commercial agriculture was in 1995. Since then, the number of GM traits used in crops has increased significantly, which in turn has increased the level of technification, as well as the number of crop species and geographic spread. In 2020, 21 countries cultivated GM crops in a commercially significant volume, totalling an estimated 198.4 million hectares (including non-traded seed). Despite the relative confinement of GM crop cultivation to a select number of countries, it is generally accepted that before GM crop varieties are commercialised for cultivation, crop varieties containing these traits must gain import approval from countries that import such crop commodities.

GM Crop-Cultivating Countries of Commercial Significance in 2020



As a result of a round of mergers and acquisitions, the number of multinational seed companies holding CropLife International membership and involved in research and development of GM traits has declined from six to four since 2017.

Key Recent Company M&A Events

M&A Event	Year
Syngenta acquired by ChemChina	2017
DuPont and Dow merge to form Corteva	2017
Bayer acquired Monsanto	2018
BASF acquired the majority of Bayer's former seed business	2018

This study was conducted in order to establish the average cost and duration of the process associated with the discovery, development and authorisation of a new biotechnology-derived genetic trait that has gained cultivation approval in two countries or more, as well as gaining import approval in at least five countries. Although the majority of commercial products contain stacked traits (i.e. contain one or more biotechnology-derived genetic traits combined through conventional breeding), the aim of the study was to focus on a single novel trait, as this eliminates any costs related to the combining of traits.

Study Definitions

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The discovery, development and authorisation of biotechnology-derived genetic traits is a complex and time-consuming process. Overall, it can be separated into three development stages, which can be further broken down into activity stages.

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The discovery, development and authorisation of biotechnology-derived genetic traits is a complex and time-consuming process. Overall, it can be separated into three development stages, which can be further broken down into activity stages.

The first stage is the discovery and identification of candidate genes that confer the desired trait, such as herbicide tolerance or insect resistance. Candidate genes can be sourced from a range of organisms or synthetically generated through modification. The identification and initial testing to demonstrate the biological activity of a candidate genetic trait occurs in the discovery phase. Only candidate genes that show sufficient biological activity are selected for further development.

Genetic Trait Development and Activity Stages

Development Stage	Activity Stages
Discovery	Early Discovery
	Late Discovery
Genetic Event Construction and Testing	Construct Optimisation
	Commercial Event Production & Selection
	Introgression, Breeding & Wide-Area Testing
Regulatory	Regulatory Science
	Registration & Regulatory Affairs

Study Definitions Continued

Candidate genetic traits that progress beyond the discovery phase into the genetic event construction and testing phase are typically combined with different promoter sequence in order to generate the most suitable genetic construct. Optimised genetic constructs are then incorporated into a specific crop for evaluation in greenhouse and field conditions. Based on the performance of these genetic constructs, the candidates with the most commercial potential are selected for introgression into the developing company's elite germplasm. The resulting crop variety is then further evaluated under field conditions to confirm the biological performance and commercial potential of the genetic trait.

The final stage of the process is the regulatory phase. Developing companies are required to submit applications to the authorities in countries where crop varieties utilising the genetic trait are intended to be cultivated, as well as in major importing countries where harvested produce, or items derived from the crop, are to be imported for food and/or feed uses. In addition, intellectual property submissions will be undertaken to patent the genetic trait and commercially protect the invention for a period of time.

Glossary of Terms

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Glossary of Terms	
Term	**Definition**
Construct	The genetic sequence created to facilitate the production of specific gene products once inserted in a cell containing, at the minimum, a promoter, a gene of interest, and a terminator
Gene expression	The generation of functional gene products from DNA/genes
Genetic event	The insertion of a particular transgene into a specific location on a chromosome
Genetic sequences	Typically, a structure comprising DNA organised into a gene or genes
Genome	Sum of the total genetic material within a cell
Hybrid	Progeny generated by crossing two different inbred lines
Introgression	The utilisation of conventional breeding methods to incorporate a genetic event into a commercial crop variety or inbred line
Promoter	A genetic sequence used to control the expression (timing and rate of transcription) of another genetic sequence
Research & Development (R&D)	The complete process of bringing a new product from discovery to the point of commercialisation
Selectable marker	A gene that is introduced into a cell, along with the gene of interest, to aid selection
Stacked trait	The combination of two traits, typically between herbicide tolerance and insect resistance
Trait	A distinguishing characteristic or quality conveyed by a gene sequence

Study Scope

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The primary aim of this study is to continue previous analysis and provide an up-to-date view on the cost and duration of the discovery, development and authorisation of a new plant biotechnologyderived trait that has received cultivation approval in at least two countries and import approvals from at least five countries.

Study Scope

Rationale

The primary aim of this study is to continue previous analysis and provide an up-to-date view on the cost and duration of the discovery, development and authorisation of a new plant biotechnologyderived trait that has received cultivation approval in at least two countries and import approvals from at least five countries. The data to be collected was intended to demonstrate the current situation according to three main categories:

- Cost of each part of the discovery, development and authorisation process.
- Time involved to complete each part of the process needed to commercialise a biotechnology-derived genetic trait.
- Total consecutive time required to bring a biotechnology-derived genetic trait from discovery to commercialisation (including authorisations).

The aim of the study was to focus on a single novel trait and exclude the time and cost to develop and gain authorisation for stacked genetic traits containing multiple genetic events.

Study Scope continued

Methods

The study was conducted in line with the protocol attached in Appendix 1. The data was collected via a questionnaire, as found in Appendix 2, which was sent to the following CropLife International member companies:

- Bayer Crop Science
- Corteva Agriscience
- Syngenta
- BASF Agricultural Solutions

The companies taking part in this study have all been involved in the recent round of mergers and acquisitions that have occurred since 2017, and, as such, they have attempted to provide as accurate information as possible based on the data they have available.

Once completed and submitted to AgbioInvestor, each response was anonymised and compiled. All data was then averaged to produce a mean value for each activity stage; however, there was a reasonable degree of variance across the responses, which is described later in this report. Where the analysis required that companies submit data for more than one crop, for example, in Part 1 of the study, data was averaged before being compiled. In the case where data was incomplete or lacked a response, mean values were calculated on a pro rata basis.

Study Results

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The primary aim of this study is to continue previous analysis and provide an up-to-date view on the cost and duration of the discovery, development and authorisation of a new plant biotechnologyderived trait that has received cultivation approval in at least two countries and import approvals from at least five countries.

Study Results

Part 1: Cost of New Plant Biotechnology-Derived Genetic Trait

CropLife International members were surveyed to establish the average cost of the discovery, development and authorisation of a new plant biotechnology-derived genetic trait that was introduced or scheduled for introduction between 2017 and 2022.

All companies surveyed have provided a response; however, due to the impact of recent mergers and acquisitions, only one of these companies is comparable to pre-2017. However, the companies have attempted to provide as accurate information as possible based on the data they have available.

In the case where a company has provided incomplete data for an activity stage, mean values were calculated for the activity stage on a pro rata basis, according to the number of responses received.

Cost of a New Plant Biotechnology-Derived Genetic Trait 2017–2022 ($ m.)

Activity Stage	Cost ($ m.)	Number of Responses
Early Discovery	2.8	3
Late Discovery	4.8	3
Construct Optimisation	13.4	4
Commercial Event Production & Selection	21.8	4
Introgression, Breeding & Wide-Area Testing	29	4
Regulatory Science	32.9	4
Registration & Regulatory Affairs	10.3	4
Total	**115**	**N/A**

Study Results Continued

Analysis of the company responses shows that mean cost associated with the discovery, development and authorisation of a new plant biotechnology-derived genetic trait introduced between 2017 and 2022 is $115.0 million.

The analysis also shows that the largest mean cost was associated with regulatory science at $32.9 million (28.6% of total costs), followed by introgression, breeding and wide-area testing with a mean cost of $29.0 million (25.2%).

When summing these activity stages into groups of discovery (early and late discovery), genetic event construction and testing (construct optimisation, commercial event production and selection, and introgression, breeding and wide-area testing), and regulatory (regulatory science and registration and regulatory affairs), genetic event construction and testing form the bulk of overall costs at $64.2 million, followed by regulatory at $43.2 million and discovery at $7.6 million.

Study Results Continued

Part 2: Time by Activity Stage (Non-Consecutive)

The second part of the study was undertaken to determine the time involved to complete each activity stage in the discovery, development and authorisation of a new plant biotechnology-derived genetic trait that was introduced or scheduled for introduction between 2017 and 2022.

As previously stated, due to the impact of recent mergers and acquisitions, companies have attempted to provide as accurate information as possible based on the data they have available.

The mean results are shown in the table below:

Duration for a Genetic Trait Commercialised Between 2017 and 2022 (Months)

Activity Stage	Duration (Months)	Number of Responses
Early Discovery	25.5	4
Late Discovery	27.7	4
Construct Optimisation	28.6	4
Commercial Event Production & Selection	35.3	4
Introgression, Breeding & Wide-Area Testing	78.6	4
Regulatory Science	112.2	4
Registration & Regulatory Affairs	92.4	4
Total	**400.1**	**N/A**

Study Results Continued

Part 3: Time by Activity Stage (Consecutive)

Part 2 of the study shows the non-consecutive time, where activity stages may overlap and run nonconsecutively; however, this does not reflect the actual duration of the overall process.

This final part of the study was intended to establish the mean actual time involved in the discovery, development and authorisation of a new plant biotechnology-derived genetic trait commercialised in the period from 2017 to 2022. The mean of the responses received from each company is shown in the following table.

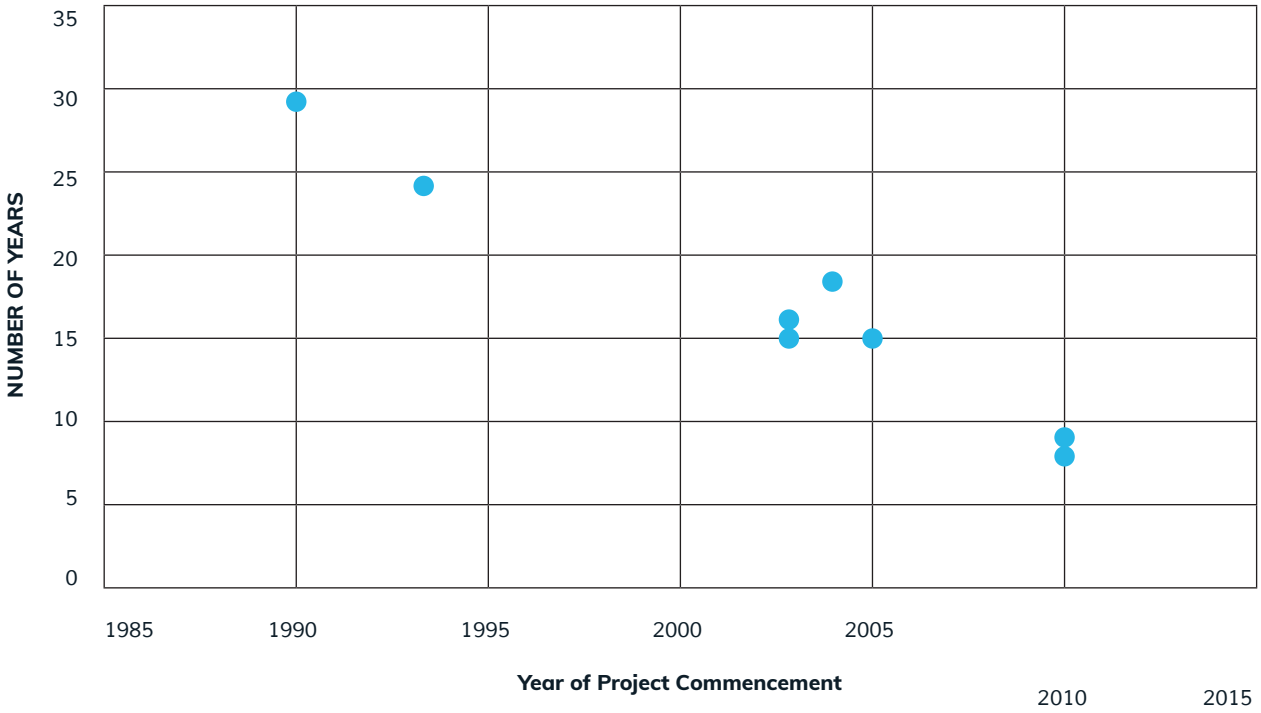
Mean Duration to Bring a Genetic Trait to the Point of Commercialisation in 2017–2022

	Maize	Soybean	Cotton	All Crops*
Months	239.5	199.5	156.0	198.3
Years	20.0	16.6	13.0	16.5

*Based on crops provided in company responses

Analysis of survey responses shows that the mean time required to bring a new plant biotechnologyderived genetic trait to the point of commercialisation was 16.5 years. However, there was considerable variation between the company responses and crop types. At the crop level, responses varied from 11.6 years to 24.0 years. Based on this analysis, cotton biotechnology-derived genetic traits took, on average, 13.0 years to be brought from early discovery to the point of commercialisation, compared to a lengthier process for soybean (16.6 years) and maize (20.0 years).

Number of Years to Bring a Genetic Trait to the Point of Commercialisation in 2017–2022 Vs Year of Commencement for Individual Crop Responses



Study Results Continued

The data in the graph above differs from that contained in the previous table, as this data refers not to mean values but to anonymised individual crop responses. The Y axis shows the number of years taken to complete the discovery, development and authorisation of a new plant biotechnologyderived genetic trait commercialised in the period from 2017 to 2022, while the X axis shows the year of project commencement. The graph clearly shows that projects initiated post-2000 are taking less time to reach the point of commercialisation compared to those initiated in the 1990's. In addition, projects initiated in the 1990's in this study took longer to complete compared to those initiated in the same time period in the study conducted in 2011, as a result of a significantly longer regulatory phase.

Discussion

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This study was conducted to establish the average cost and duration of the process associated with the discovery, development and authorisation of a new biotechnology-derived genetic trait that has gained approval in two countries or more, as well as gaining import approval in at least five countries.

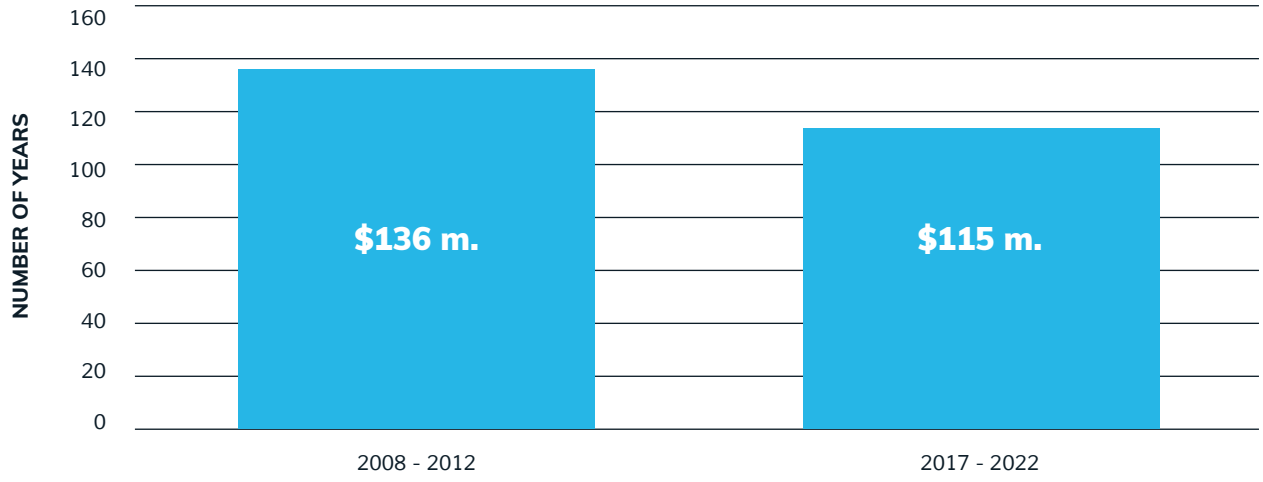
Discussion

This study was conducted to establish the average cost and duration of the process associated with the discovery, development and authorisation of a new biotechnology-derived genetic trait that has gained approval in two countries or more, as well as gaining import approval in at least five countries.

The companies taking part in this study account for the majority of the commercialised GM traits used in agriculture today. These companies were provided with a questionnaire, the responses to which were anonymised, and the mean values established.

The results of the study indicate that the cost of bringing a new biotechnology-derived genetic trait to the point of commercialisation between 2017 and 2022 was on average $115 million. In comparison to the previous CropLife International study that estimated the same costs, the analysis shows that the average cost has fallen from $136 million in the 2008–2012 period to the current value of $115 million, indicating a cost reduction of 15.4%.

Cost to Bring a Genetic Trait to the Point of Commercialisation by Period of Introduction



Discussion Continued

Within this, the majority of costs in the 2017–2022 period were directed at genetic event construction and testing (construct optimisation, commercial event production and selection, and introgression, breeding and wide-area testing) at $64.2 million, representing 55.8% of total costs. Following this, regulatory activities (regulatory science and registration and regulatory affairs) required an average of $43.2 million, 37.6% of total costs, with the remaining $7.6 million (6.6% of total costs) directed at discovery (early and late discovery).

The proportion of R&D expenditure between development categories has changed from that indicated in the previous study. While genetic event construction and testing have broadly remained comparable at 55.8% of total costs, the proportion required to fulfil regulatory activities has increased significantly to 37.6% of total costs; this higher proportional spend has come at the expense of expenditure in the discovery phase, which has fallen from 22.8% of total costs in 2008–2012 to just 6.6% in 2017–2022.

Total Costs Attributed to Each Development Category ($ m.)				
Development Category	**2008-2012**	**%**	**2017-2022**	**%**
Discovery	31.0	22.8	7.6	6.6
Genetic Event Construction and Testing	69.9	51.4	64.2	55.8
Regulatory	35.1	25.8	43.2	37.6
Total	**136.0**	**100.0**	**115.0**	**100.0**

Discussion Continued

The study was also designed to show the time associated with bringing a new biotechnology-derived genetic trait to the point of commercialisation. Analysis of the submitted data shows that the nonconsecutive time required to complete the process was approximately 400.1 months for genetic traits brought to the point of commercialisation in 2017–2022. This is significantly longer than the 234.1 months described for the genetic traits brought to the point of commercialisation in 2008–2012. When summing activity stages into development categories, it is clear that the greatest proportion of time spent is in the regulatory phase with a total of 204.5 months, representing 51.1% of the total time required to complete the R&D process. An average of 142.4 months (35.6%) was required to complete the genetic event construction and testing phase, with the remaining 53.2 months (13.3%) spent on the discovery phase.

Non-Consecutive Time Attributed to Each Development Category (months)				
Development Category	**2008-2012**	**%**	**2017-2022**	**%**
Discovery	53.9	23.0	53.2	13.3
Genetic Event Construction and Testing	94.2	40.2	142.4	35.6
Regulatory	86.0	36.7	204.5	51.1
Total	**234.1**	**100.0**	**400.1**	**100.0**

Discussion Continued

In comparison to the previous study, it is evident that the duration of the regulatory phase for genetic traits reaching the point of commercialisation in the 2017–2022 period has increased significantly, approaching the duration of the entire R&D process for genetic traits reaching the point of commercialisation in the 2008–2012 period.

As with total costs, the non-consecutive duration of the genetic event construction and testing phase remained the closest to the previous study values at 35.6% of the time. The time spent in the discovery phase, meanwhile, has decreased from 23.0% in 2008–2012 to just 13.3% in 2017–2022.

While the summed duration of the non-consecutive activity stages does not accurately describe the total duration of the R&D process, it is indicative of the duration from project commencement to completion, and it is included to show the duration of each incremental activity stage.

Companies were also asked to quantify the total duration of the R&D process in bringing a new biotechnology-derived genetic trait to the point of commercialisation. These responses were averaged to establish the mean duration of 16.5 years for a genetic trait commercialised between 2017 and 2022.

Mean Duration to Bring a Genetic Trait to the Point of Commercialisation by Crop and Period of Introduction (Years)			
Crop	**2008-2012**	**2017-2022**	**% Change**
Maize	12.0	20.0	66.3
Soybean	16.3	16.6	1.8
Cotton	12.7	13.0	2.4
Canola	11.7	N/A	N/A
All Crops	**13.1**	**16.5**	**26.0**
All Crops Excluding Canola	**13.7**	**16.5**	**20.7**

Discussion Continued

The table above compares the mean duration to bring a genetic trait to the point of commercialisation by crop, for the periods 2008–2012 and 2017–2022. At the "all crop" level, the analysis shows that the mean duration has increased by 26.0%, with the greatest increase in duration for maize (+66.3%), followed by cotton (+2.4%) and soybean (+1.8%). Responses in the latest survey did not include any for canola; when excluding canola responses from the previous study, the mean duration for all crops rose by 20.7%.

It is evident from the analysis of the submitted data showing the non-consecutive time required to complete the R&D process that the primary reason for the sharp rise in overall duration is the greatly increased period required to complete the regulatory process. However, a secondary contributing factor is the large rise in the time required to complete the introgression, breeding and wide-area testing activity stage.

Key Results of the Study

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Key Results of the Study

- The cost of discovery, development and authorisation of a new plant biotechnology-derived genetic trait commercialised in the period from 2017 to 2022 is $115.0 million.
- The discovery phase of the process accounted for 6.6% of total costs and 13.3% of the non-consecutive total time.
- The genetic event construction and testing phase represented 55.8% of total costs and 35.6% of the non-consecutive total time.
- The regulatory phase, the longest duration of the overall process, accounted for 37.6% of total costs and 51.1% of the non-consecutive total time.
- The mean duration to bring a genetic trait to the point of commercialisation in 2017–2022 was 16.5 years. However, this study did not assess the time required to develop stacked trait varieties, which commonly represent commercial seed product offerings.
- As indicated by a comparison with the previous study, the cost of discovery, development and authorisation of a new plant biotechnology-derived genetic trait has declined from $136 million in the 2008–2012 period to the current value of $115 million, whilst the time required to complete the process has increased from 13.1 years to 16.5 years.

April 2022

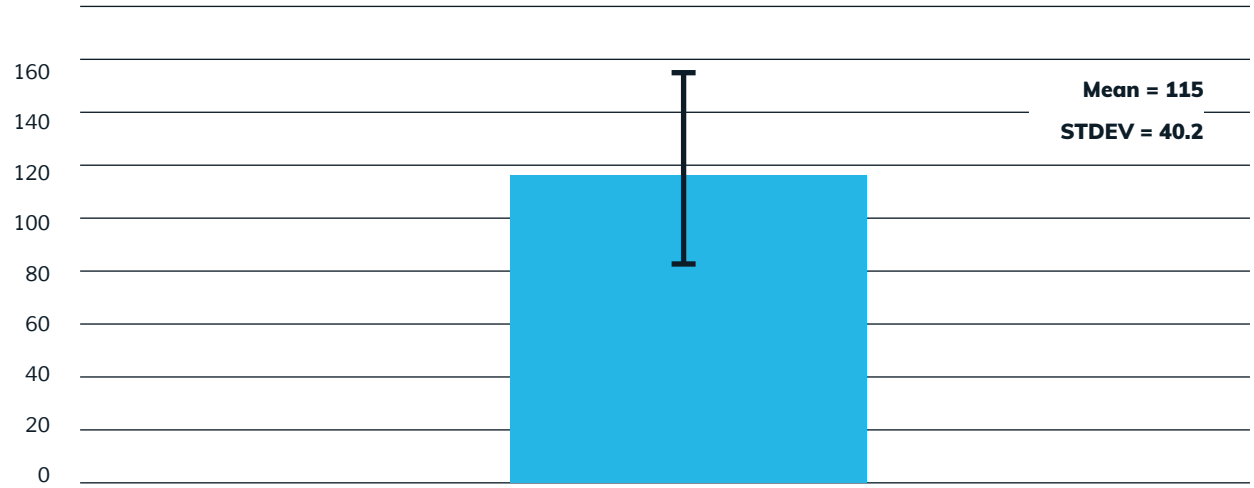
Survey Repsonse Variance

09

Survey Response Variance

As described in Methods, participating companies were surveyed to establish a mean cost for the discovery, development and authorisation of a new plant biotechnology-derived genetic trait that was introduced or scheduled for introduction between 2017 and 2022.

Cost to Bring a Genetic Trait to the Point of Commercialisation 2017–2022 ($ m.)



The graph above shows the mean cost to bring a genetic trait to the point of commercialisation between 2017 and 2022, compared to the standard deviation of responses. The graph highlights the variation in the survey responses; however, this is not unexpected, as each company may have a different commercial strategy that ultimately dictates R&D expenditure and/or difference in crop focus, thus leading to significant differences in the cost of genetic trait development.

Appendix 1: Study Plan

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All information provided by respondents will be anonymised, with all data in the final published report being mean values.

Company Information

All information provided by respondents will be anonymised, with all data in the final published report being mean values.

Please provide the name of the company and the currency used in responses to the questionnaire. Any non-US dollar currencies will be converted to US dollars using average yearly exchange rates.

Company Name	
Currency Used	

Summary

10

The primary aim of this study is to continue previous analysis and provide an up-to-date view on the cost and duration associated with the discovery, development and authorisation of a new plant biotechnology-derived trait that has received cultivation approval in at least two countries and import approvals from at least five countries.

Summary

The primary aim of this study is to continue previous analysis and provide an up-to-date view on the cost and duration associated with the discovery, development and authorisation of a new plant biotechnology-derived trait that has received cultivation approval in at least two countries and import approvals from at least five countries.

The leading R&D-focused seed companies are being asked to participate in a black box study by providing data via a questionnaire. The questionnaire is separated into three sections: **Cost, Time by Activity Stage (non-consecutive)** and **Time by Activity Stage (consecutive).**

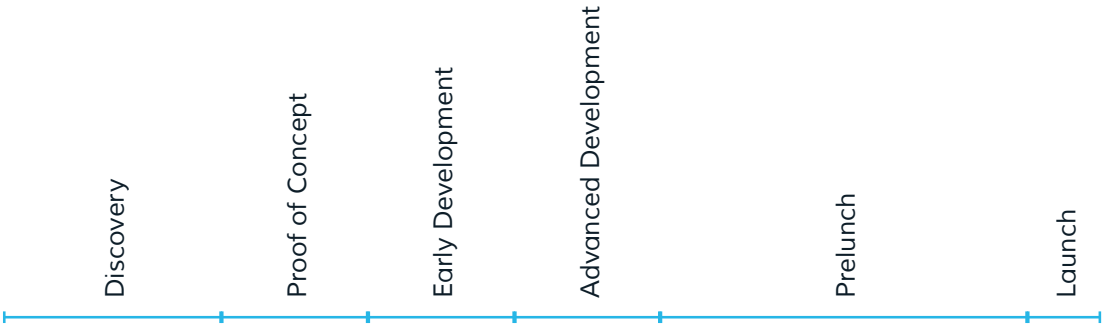
Part 1: Cost – shows the level of expenditure in each of the activity stages.

Part 2: Time by Activity Stage (Non-Consecutive) – describes the incremental length of time required to complete each individual activity stage, measured in months. As activity stages may occur simultaneously, the sum total of time spent in each activity stage may be in excess of the total linear time.

Part 3: Time by Activity Stage (Consecutive) – describes the total (actual) length of time required to successfully bring a biotechnology-derived trait from discovery to commercialisation, measured in years and by crop.

Summary Continued

Example of How Activity Stages May Be Segmented by Year



R&D Phases															
Years for R&D	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Activity Stages															
Early Discovery															
Late Discovery															
Construct Optimisation															
Commerical Event Production & Selection															
Introgression, Breeding * Wide-Area Testing															
Regulatory Science															
Registration & Regulatory Affairs															

Appendix 2: Questionnaire

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The data in this section will be used to illustrate the level of expenditure at each activity stage as well as the total spent on bringing a biotechnology-derived trait from discovery to commercialisation.

Questionnaire

Part 1: Cost

The data in this section will be used to illustrate the level of expenditure at each activity stage as well as the total spent on bringing a biotechnology-derived trait from discovery to commercialisation.

1. The event may be commercialised as a single trait or as part of a stacked trait product.
2. Provide the compiled total expenditure to cover all costs associated with the activities defined in each activity stage.
3. If the compiled expenditure information spans two or more of the activity stages, please provide the value and indicate the relevant activity stages represented by the value given.
4. If unable to provide a single value investment estimate, please provide a range where the total range is no more than 10% of the median of the range.
5. Provide cost estimates on a fully loaded basis to include as many of the following as possible:
    a. R&D staff
    b. General R&D operating costs
    c. External R&D collaboration, contract and testing costs
    d. Capital depreciation for the R&D facilities required to execute the work
    e. R&D collaboration costs for any activity stages
    f. Upfront payments and/or royalties for inward licensed events, technologies or components specific to the trait
    g. Costs to discover and develop promoters and selectable markers used to generate the events (total if unique to the event or pro-rata if used for multiple events).

Questionnaire Continued

6. For e. and f. above, please allocate the costs to the activity stage(s) in which the comparable inhouse activity would normally take place.

7. Do not include the following costs:

a. Further discovery and development activities to generate back-up genes and events represented in this study until the "winner" reached the marketplace

b. Breeding and development costs for stacks containing the event

c. Costs for biotechnology affairs, government affairs, industry affairs and public acceptance to enable the commercial launch of a product

d. Direct capital expenditures (capital represented on a depreciated basis; see #5d above)

e. Commercial seed production costs

f. Amortisation of merger or acquisition costs

g. Post commercial launch development

h. Product monitoring and stewardship

i. Patent and litigation costs

j. Sales and marketing costs

8. Please indicate on the form the fully loaded basis for the costs you are reporting.

9. Provide costs in your local currency. This will be converted during the process.

Questionnaire

Part 2: Time by Activity Stage (Non-Consecutive)

The data provided in this section will be used to show how long it takes to complete each activity stage in isolation. The questionnaire asks for data for biotechnology-derived traits commercialised in the five years between 2012 and 2017, as well as a comparable trait commercialised from 2017 to the present day.

Please provide an estimate for the length of time it took to complete each activity stage. When responding with data for the time period 2012–2017, please use the same trait used in Part 1. Please provide duration in months.

For traits that have been discovered by another company and are now in possession either through inward licensing or as a result of acquisition, please complete the questionnaire by estimating when the trait entered activity stage 1. Any trait inward licensed or acquired, please asterisk.

†Same genetic event used when responding in Part 1
Note: any inward licensed or acquired event, please asterisk

Activity Stage	Duration of an event commercialised between 2012 & 2017†	Duration of an event commercialised from 2017–present
1. Early Discovery		
2. Late Discovery		
3. Construct Optimisation		
4. Commercial Event Production & Selection		
5. Introgression, Breeding & Wide-Area Testing		
6. Regulatory Science		
7. Registration & Regulatory Affairs		

Questionnaire

Part 3: Time by Activity Stage (Consecutive)

The data in this section will be used to show the total time taken to bring a biotechnology-derived trait from discovery to commercialisation.

As a result of the overlapping nature of the activity stages during the R&D process, the total time taken to bring a trait from discovery to commercialisation cannot be calculated from the data in Part 2. Please estimate the total time taken to bring a trait from discovery to commercialisation in years. For traits still in the research phase that are scheduled to be commercialised no later than 2022, please estimate future time scales.

For traits that have been discovered by another company and are now in possession either through inward licensing or as a result of acquisition, please complete the questionnaire by estimating when the event entered activity stage 1. Any event inward licensed or acquired, please asterisk.

Note: any inward licensed or acquired event, please asterisk

Trait	Crop	Month and Year of Start of Activity Stage 1	Month and Year of Commercialisation
1			
2			
3			
4			
5			
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